Policies and Procedures

for

Research and Other Sponsored Activities

Revised January 2018

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ABOUT THIS MANUAL

PURPOSE

The purpose of this Manual is to provide assistance and guidance to faculty and staff who are involved in the preparation of proposals to and in the administration of awards received from external sponsors. This Manual:

- Defines the responsibilities of principal investigators/project directors for the preparation, review, management and reporting requirements of sponsored programs;
- Emphasizes the necessity for uniform and consistent financial accountability and documentation in proposal budgets;
- Defines the Health Science Center's criteria for acceptance of sponsored program awards;
- Discusses the various regulatory compliance requirements commensurate with the acceptance of sponsored program funding.

Throughout the Manual, references to other Health Science Center policies and procedures relevant to the academic and research conduct of investigators and others involved in sponsored programs proposals and administration are cited. All persons should be familiar with the *Regent's Rules and Regulations,* the *Handbook of Operating Procedures*, and any other policy guidelines that have been issued by The University of Texas System or the Health Science Center in general.

REVISIONS

As chapters or sections are updated, added, or deleted, the Office of Sponsored Programs (OSP) will announce revisions to the Manual on its listserv. To be added to the listserv please contact OSP at grants@uthscsa.edu. New or revised sections will also be identified in the Table of Contents.

CONSISTENCY WITH OTHER HEALTH SCIENCE CENTER ISSUANCES

While this Manual is a compilation of the various Health Science Center policies related to research and other sponsored activities and should be used by those involved in the administration of sponsored activities, any specific differences between the policies

cited in this Manual and the Health Science Center *Handbook of Operating Procedures* shall be resolved in favor of the *Handbook of Operating Procedures*.

TERMS USED INTERCHANGEABLY IN THIS DOCUMENT

Throughout this document there are many terms or acronyms which are used interchangeably but convey the same meaning. A partial listing of these is as follows:

> Principal Investigator/Project Director - PI/PD - Principal Investigator - Investigator - PI
>
> Indirect Costs - Facilities and Administrative Costs - IDC - F&A - Overhead

✉ Appendix A contains a listing of acronyms commonly used when referring to federal programs and sponsored programs administration.

USEFUL ICONS

Icons have been placed throughout this Manual to highlight key information. The key to these icons is as follows:

- 🗁 Important Policy or Procedure
- ✎ Example
- 🗎 Form
- ✉ Appendix

CONTACT INFORMATION

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Located at the Research Administration Building (RAB), Room 2.204 on the North Campus, 8403 Floyd Cure Drive.

E-mail: **grants@uthscsa.edu** · Website: **http://research.uthscsa.edu/osp/**

CHAPTER ONE

OVERVIEW OF RESEARCH AND OTHER SPONSORED ACTIVITIES

1.1 Sponsored Activities at UT Health San Antonio

Sponsored activities at the Health Science Center encompass a broad range of projects from basic laboratory research to clinical drug studies; from training grants to outreach programs from the community; and many other activities. Funding for these programs is housed in the Health Science Center's 41xxx-44xxx fund group series or, in some cases, in other account series 48002 (clinical research studies), 48007 (federal clinical studies), 14xxx (direct state appropriated funding for projects), "15xxx" (Texas Higher Education Coordinating Board Grants), and "23xxx" (institutional grant funds).

1.2 What is a Sponsored Activity?

For a project to be considered a sponsored activity at the Health Science Center and, to be subject to the policies and procedures of this Manual, a project should have one or more of the following characteristics:

a) Payment is contingent upon the delivery of a specific tangible item, such as a report, samples, a data set, assays or prototype, or the achievement of specific performance targets.
b) There is a line item budget detailing or limiting expenses by activity, function, or project period or limiting the freedom to transfer funds among expenditure categories.
c) A detailed financial report, certified voucher, federal single audit or external audit is required.
d) Any unexpended funds must be returned to the sponsor at the end of a project period.
e) The proposed agreement provides for the disposition of intellectual property (e.g., copyrights, patents, or licenses).

f) The proposed activity involves government-supported construction, alteration, renovation or acquisition of equipment or facilities.
g) The proposed budget includes payment of Health Science Center indirect costs by the sponsor.

1.3 Roles and Responsibilities 

Throughout the proposal, conduct, and reporting of a sponsored project, various individuals have roles and responsibilities relating to that project. Those roles and responsibilities include, but are not limited to:

Principal Investigator/Project Director
Responsible for the preparation of proposals to external funding organizations and assuring that the information contained therein is accurate and correct to the best of his/her knowledge. Responsible for ensuring the appropriateness of all charges on sponsored projects, including those of any subawards. Ensure the consistent application of direct costing practices to their sponsored projects with the assistance of the academic department administrator and the Office of Sponsored Programs. Determine, justify, and document the circumstances in the budget proposal narrative or during the project when costs normally charged as indirect are charged as direct. Document special support costs in proposal budgets. Submit required technical project reports and other project deliverables as required by the sponsor in a timely manner.

Department Administrator (or designee)
Assist principal investigators/project directors in the administration of their projects in making appropriate charges to sponsored project accounts, and in determining and justifying circumstances when costs normally charged as indirect are charged as direct. Ensure consistency of charging practices within the unit, review sponsored project proposals for justification of direct charges requested, especially when costs normally charged as indirect are proposed as direct charges. In conjunction with principal investigators/project directors, review and maintain financial records for appropriateness of charges and for reviews by internal or external auditors.

Dean/Department Chair
Establish effective processes and controls that will ensure compliance with the policies and procedures of the Health Science Center, including those enumerated in this Manual. Communicate these practices to all responsible employees within their colleges and departments. Approve funding proposals and/or agreements for sponsored programs.

Internal Service Centers
Follow the policies and practices of the Health Science Center, including those enumerated in this Manual, when developing rates and billing Project IDs.

Office of Sponsored Programs (OSP)
Responsible for institutional review and signoff of proposals, negotiation and review of award agreements, establishing accurate Project IDs, subaward preparation and monitoring, advising on postaward business and financial matters, preparing accurate and complete financial reports, and Project ID closeout. Responsible for enforcing costing and other administrative policies of the Health Science Center and its external sponsors.

Office of Accounting
Responsible for preparation of periodic billings and reports, assessing cash position on cost reimbursable projects, processing of stipend payments, drawdown of federal funds and Project ID closeout. Responsible for insuring compliance with internal and external rules and regulations.

Internal Audit
Independently evaluate compliance with federal regulatory policies and institutional practices to insure a proper system of internal controls is in place at the departmental and institutional levels.

Office of Regulatory Affairs & Compliance
Responsible for ensuring an effective training and monitoring program is in place to address high risk areas of potential noncompliance. The Chief Compliance Officer, with the aid of the Compliance & Ethics Committee, is responsible for implementing and monitoring a continuous and proactive compliance function for the University.

1.4 Who Can Be a Principal Investigator/Project Director

As outlined in the HOP Section 7.1.1, The "Principal Investigator" shall encompass the terms Principal Investigator, Project Director, Program Director, and similar titles, and shall mean a single individual who, in the event of an award from an external funding sponsor, shall have the full and final responsibility for the conduct of the project as proposed. Employees eligible to be Principal Investigators must hold a salaried appointment position at UT Health San Antonio. There is not a minimum appointment percentage or position title required; the only requirement is that the individual must have a paid appointment for which UT Health San Antonio directly pays. The only exception is for Adjoint faculty appointments where a memorandum of understanding (MOU) has been executed with the partnership organization as outlined in Section 3.1.1 "Academic Titles" in the *Handbook of Operating Procedures* (HOP). Adjunct faculty are not allowed to hold the title of Principal Investigator due to issues that include

compensation documentation, conflict of interest, intellectual property ownership and lastly a lack of control of the individual since they do hold an actual salaried faculty appointment.

1.5 Intentionally Left Blank

1.6 Office of Sponsored Programs ✉

The Office of Sponsored Programs is charged with providing the campus community with administrative support in the areas of pre-award, contract negotiation, and post-award sponsored projects administration. Within that arena, the Office assists in identifying sources of project funding, provides institutional review and endorsement of proposals, reviews and negotiates agreements, establishes new Project IDs, prepares sub-awards, provides post-award business and financial assistance and approvals, performs compliance training and other activities for adherence to Health Science Center, federal, and other sponsor regulations, and prepares financial and other non-technical closeout reports. The Office also has other functions within the Health Science Center's restricted fund groups including the preparation and negotiation of the facilities and administrative (indirect cost rate). A listing of OSP staff and their primary duties is available at http://research.uthscsa.edu/osp/staff.shtml.

CHAPTER TWO

PRE-PROPOSAL ACTIVITIES

2.1 Finding Sources of Project Funding

The Office of Sponsored Programs has a number of resources available to provide information on potential sources of project funding. Among them are:

PROGRAM ANNOUNCEMENTS AND FORMS
Copies of program and announcements and forms can be obtained from the OSP website under Current Funding Opportunities. In addition, the OSP manages a funding opportunities email listserv for which investigators across campus can sign up. You can email grants@uthscsa.edu to have an investigator including on our funding listserv. This is especially helpful for our junior faculty.

GENIUS/SMARTS
GENIUS/SMARTS is a comprehensive database developed by InfoEd International, Inc. GENIUS, Global Expertise Network for Industry, Universities, and Scholars, is a global-web-based network and database of scientific and scholarly expertise. GENIUS contains primary source profiles of scholars and researchers at leading universities and research institutions through the world, including those at the Health Science Center. SMARTS, SPIN Matching and Research Transmittal System, provides faculty with a comprehensive, targeted electronic link to comprehensive current U.S. federal and non-federal as well as international research funding information.

Faculty and other scholars at the Health Science Center may submit their information to GENUIS through a website located by first accessing the OSP webpage at http://research.uthscsa.edu/osp. By registering and entering certain data, including research interests and keywords, SMARTS will automatically transmit funding opportunity information to the individual's e-mail address.

SPIN
The Sponsored Programs Information Network (SPIN) is a computer database containing current, detailed information about thousands of government and private funding opportunities. SPIN searches can be accessed either through the OSP Grants Specialist or directly at the OSP webpage at http://research.uthscsa.edu/osp.

OSP Web Site
The OSP website provides extensive links to funding information, agencies, and programs. The site is found at: http://research.uthscsa.edu/osp. Government, non-federal and private agency links can be found at the *Funding Opportunities* section.

OSP ListServ
In order to more effectively disseminate information in a timely fashion, OSP maintains an electronic mailing list which targets Health Science Center faculty and administrators. The list is a traditional ListServ, whereby a message sent to the ListServ address is broadcast to the subscribers on the list. You can sign up by sending an email request to grants@uthscsa.edu.

2.2 Student Support and Fellowships

Students seeking funding information should first check with their department and the following offices:

Office of Financial Aid
The Office of Financial Aid offers financial aid advising and processes loans and awards, scholarship and grants.

Associate Deans
Each of the Health Science Center Schools have designated Associate Deans for Students or Student Affairs who can provide information to students in their schools about available student support and fellowships.

In addition, the OSP has some limited information regarding graduate student fellowships. Graduate students may also avail themselves of the electronic information available through the OSP Web Site.

2.3 Limited Proposal Submissions

Some programs contain restrictions that limit the number of applications per institution. The Health Science Center has institutional policies in place for selecting nominees/candidates for these programs and vests administrative support responsibility for these restricted-submission programs in the OSP. The Vice President for Research manages the candidate selection process for limited submission programs from more than one School. A Limited Proposal Submission Matrix lists the most common limited

submission programs, their limits, and the nomination/selection process and is available on the OSP website at http://research.uthscsa.edu/osp/forms/restricted.xls.

2.4 Institutional Grant Programs

There are a number of grant programs funded internally through the Health Science Center. These include the grants programs under the cognizance of the Vice President for Research. Information on these programs is generally available in OSP.

CHAPTER THREE

PROPOSAL DEVELOPMENT AND COSTING

3.1 Types of Proposals

What is a Proposal

A proposal may be submitted in many different formats and types but it is generally a request for financial assistance, payment for services rendered, or loan of equipment. Proposals generally contain a technical description of the work or activity to be performed and a request for financial assistance (budget).

Preliminary Proposals

Preliminary proposals or "white papers" are abbreviated descriptions of the proposed project. A sponsor often requests preliminary proposals when large programs are proposed and usually include an estimated budget.

Preliminary proposals are not formal commitments by the Health Science Center. In general the Certificate of Proposal (as described in Section 4.3) is not required. However, a copy of a preliminary proposal should be furnished to the appropriate Department Chair or Academic Director's Office. If the preliminary proposal contains substantial cost-sharing contributions and/or commitments, the appropriate Chair or Academic Director should be consulted for his/her agreement to such commitments. If the sponsor requests a formal proposal, refer to Chapter Four for processing procedures.

Formal Proposals

Formal proposals, all of which require review and endorsement by the Health Science Center, can be any of the following:

- *Solicited Proposal*. Submitted to a specific program and responds to sponsor requirements and guidelines.

- *Unsolicited Proposal*. Developed independently by the principal investigator/project director in accordance with his/her field of technical expertise and submitted to an appropriate funding sponsor. May or may not

be subject to non-routine requirements as specified in a program announcement.

- *Response to a Request for Proposals (RFP)*. Submitted in response to a specific work statement developed by the sponsor. RFP's generally have a fixed response time, contain proposed contract provisions, and require lengthy certifications to be completed.

Note

OSP should be notified as soon as possible when intending to submit a response to an RFP. OSP will need to review proposed contract provisions as exceptions can normally be stated only at the time of proposal submission. In addition, OSP will require adequate time to complete any necessary representations, certifications, and other special RFP business requirements.

- *Renewal Proposal*: A renewal proposal is a formal request for continued funding of a project where the project funding period is ending. These proposals are normally subject to the same sponsor review criteria as new proposals. Renewals must be routed through the standard University proposal approval and sign-off process.

- *Non-competing Grant Progress Reports*: Requests for the next period's funding within a multi-year grant or approved project period. These reports are generally brief and usually consist of a report on the technical progress of the project and, if required, a budget and other relevant materials. Non-competing grant progress reports may require institutional endorsement by OSP, as specified by the Sponsor. For Project ID establishment purposes, budgets are typically required by OSP even though they may not be submitted to the sponsor.

3.2 General Information Required on Proposals ✉

Certain information is required on almost all proposals, particularly those submitted to federal sponsors. A listing of information that may be useful in preparing a proposal is available on the OSP website at http://research.uthscsa.edu/osp/propinfo.shtml.

3.3 General Format

Most sponsors provide standard application forms and prescribe rigid rules for proposal format including indicating that the designated format and/or forms must be used or else the proposal could be returned without review. For sponsors that do not require a prescribed format, the following items comprise a standard proposal format.

Transmittal Letter
If a transmittal letter by an authorized official of the Health Science Center is required, OSP will prepare the letter using information provided on the Certificate of Proposal. Alternatively, the PI/PD may elect to write the transmittal letter, which will be reviewed by OSP.

Cover Page ✉

The cover page should contain enough information to clearly identify the proposed project and relevant parties and contacts. A sample cover page is located at Appendix D.

Abstract
Most sponsors require an abstract of approximately 200 words that outlines the proposed scope of work, methods, and significance of the project. The abstract should be written in plain English and fit for public disclosure.

Statement of Work
The statement of work is a complete and detailed explanation of the proposed project, including general background, proposed methodology, goals and objectives, significant milestones, available preliminary data, and any other items relevant to presenting a detailed plan of the proposed work.

Personnel
Project personnel and their responsibilities must be identified and the effort proposed must be presented.

Biographical Sketches/Curriculum Vitae
Current vitae for all key personnel and consultants should be included.

Current and Pending Support
Some sponsors require a listing of each key personnel's listing of pending proposals and current awards. This information should include the percentage of effort devoted to these other projects and an explanation of any relevant scientific or budgetary overlap.

Facilities and Equipment
This section describes equipment or other relevant Health Science Center resources that will be available to the project and that offer unique advantages to the proposed research.

Budget and Budget Justification
Developing an accurate budget acceptable to the sponsor and which matches the activities to be conducted is critical. Budget development and costing guidelines are discussed fully in Sections 3.4 and 3.5.

Appendices
Appendices may include letters of endorsement or cooperation, previous publications, or other materials that are relevant and would enhance the proposal.

3.4 Budget Development

Overview

In submitting proposals for funding by external agencies, the Health Science Center follows the principles and requirements of the federal Office of Management and Budget (OMB) Uniform Guidance. Consequently, when constructing a budget, the Principal Investigator/Project Director or other budget preparer should be mindful that any proposed costs must be *reasonable*, *allocable*, and be *consistent* with Health Science Center general costing policies. Additionally, when proposing to federal agencies, costs cannot be proposed which are unallowable in OMB Uniform Guidance. Examples of those costs include alcoholic beverages, donations and contributions, memberships (including memberships to professional societies), and entertainment costs.

In addition, OMB Uniform Guidance limits reimbursement for certain types of expenses that the government considers administrative. Included in those expenses are costs of administrative and clerical staff, postage costs, telephone costs, and routine office supplies. These costs are only appropriate when they are absolutely essential to the project's success and are provided for the sole benefit of the project. Proposal budgets that include these items must contain well-documented justifications. Further information about the allowability of those costs can be found in Sections 3.5 and 6.1 of this Manual.

Cost Categories

There are three important categories of costs associated with most proposal budgets. These are *direct costs, modified total direct costs,* and *facilities and administrative (indirect) costs*.

Direct Costs

Direct costs are those expenses that can be directly identified with a particular project. Categories of direct costs may include salaries and wages, benefits, consultants, subawards, equipment, supplies and travel. Other allowable direct costs are described in OMB Uniform Guidance, or in the sponsor's own application guidelines.

Modified Total Direct Costs (MTDC)

MTDC is a subset of direct costs and is the base to which facilities and administrative (indirect) costs are applied on most proposals. (There are many exceptions; consequently, the sponsor's application guidelines should be consulted.) Primarily used in budgets for federal funding, MTDC is equal to total costs less any tuition and fees, capital equipment (items of equipment whose acquisition cost exceeds $5,000), lease or rental of facilities or equipment, renovation, patient care expenses, and subaward expenditures in excess of $25,000. An example of the application of MTDC is described in Example 3.5.

Facilities & Administrative (F&A) Costs

Facilities & Administrative (F&A) costs also sometimes referred as indirect costs are those costs which are not easily identified with a particular project and include such categories as utility costs, depreciation of buildings and equipment, operations and maintenance expenses, general administrative expenses, and library costs.

F&A costs must be requested at the Health Science Center's current negotiated rate, on or off campus, unless restricted by agency regulations. Further discussion of F&A costs is contained later in this chapter.

Note

Waivers of F&A (indirect) costs can only be approved Chief Financial Officer using the waiver process that can be found at http://www.uthscsa.edu/hop2000/7.1.2.pdf. All requests for a waiver should be submitted through the Office of Sponsored Programs and be endorsed by the Department Chair/Institute Director, Dean and Vice President for Research.

3.5 Budget and Cost Guidelines ✉

Following is a guideline of how to develop proposal budgets and how to calculate Health Science Center costs. In addition, a *Proposal Budgeting Information Table* has been provided as Appendix E. This table contains current rates and costs for proposal preparation as well as other useful information often required in sponsor applications. In addition, the *Proposal Budgeting Information Table* contains current escalation factors that are recommended for developing costs for future project years. This information is regularly updated at the OSP website (http://research.uthscsa.edu/osp).

> **Note**
>
> The National Institutes of Health has instituted procedures for more research grant proposals with direct costs of $250,000/year or less to be submitted through the *Modular Grants Format*. Information and guidance for the NIH Modular Grants can be found at the OSP website at http://research.uthscsa.edu/osp.

The proposal budget should reflect an accurate assessment of the essential project costs that are allowable and reasonable for the proposed project. Current and complete cost estimates and documentation used in these estimates must be kept by the budget preparer as support for the reasonableness of the request to the sponsor. This is especially important if the proposal undergoes a pre-award audit; such audits are typically done only for large proposals. Sponsor requestd for additional budget information or pre-award audits should be coordinated through OSP.

SALARIES

The salary section of the proposed budget should indicate the personnel working on the project, their role, the percentage of effort to be devoted to the project, and the salary anticipated to be charged to the project. The percentage of effort proposed should normally correlate to the salary requested; uncompensated salary is considered cost sharing and treated in accordance with Health Science Center policy (see Section 3.6). Unless otherwise stated, all salaries should be budgeted at current base salary levels and include projected increases consistent with the escalation factors cited in the *Proposal Budgeting Information Table*. If a promotion is anticipated during the project period, the appropriate salary increase should be projected in the applicable year of the project and fully justified. In general, all key personnel (Principal Investigators, Project Directors, Senior Scientists and Researchers) should be named. Specific salary guidelines follow:

Faculty Salary

The majority of faculty at the Health Science Center are typically appointed on a twelve-month basis. However, some appointments may be made on a nine-

month basis. The base for the salary must be applied appropriately in the proposal budget.

Calculating Salaries
The following examples have been provided to illustrate how to calculate salaries on proposal budgets.

Example 3-1 Salary
Assistant Professor Jones is currently earning $60,000 for a twelve-month appointment. She will expend 25% effort on the proposed project. Assistant Professor Jones' salary is calculated as follows:

Step 1) Determine Professor Jones' salary for the start date of the project.

Step 2) Multiply the projected salary by 25% effort.

$62,400 x .25 = $15,600

Note that fringe benefits have not yet been calculated (these are generally shown as a separate item from salary). Subsequent years should be calculated at the Health Science Center's suggested escalation factor of 4%. (NIH restricts salary escalation to 3% per year.)

Example 3-2 DHHS Salary Cap
Dr. Smith has a twelve-month appointment in the Medical School with a projected base salary of $150,000. He will expend 33% effort on an NIH project for the year.

Step 1) Because NIH has a salary cap of $189,600 (as of 01/07/18), the salary cap should be multiplied by 33% to determine the total salary request for the grant year.

$189,600 x .33 = $62,568 (total salary request)

Step 2) If Dr. Smith were to expend 33% effort for anything less than the full 12 months, the monthly salary based on the salary cap should first be calculated:

$189,600 ÷ 12 = $15,800 (monthly salary)

Step 3) Multiply the monthly salary by the number of months:

$15,800 x 7 months = $110,600

Step 4) Determine the 33% effort:

$110,600 x .33 = $36,498 (total salary request)

Note

Other sponsors have salary caps such as CPRIT and PCORI.

Example 3-3 Person Months

As federal sponsors move toward submission of proposals on Grants.gov, they now ask for a calculation of person months on the project rather than percentage of effort. To calculate person months, multiply the percentage of effort by the number of months of support requested.

For a twelve-month appointment and expended effort of 10% per year, the person months would be calculated by multiplying .10 by 12 months with a result of 1.2 person months.

For a nine-month appointment which requests effort of 10% per year and 100% effort for two months summer, the calculation would be 10% x 9 months which equals .9 months plus 2 months (summer) for total person months of 2.9 months.

Veteran's Administration Appointments ✉

Some faculty have appointments in both the Health Science Center and the Veterans Administration. Federal granting agencies will not pay salary support for the VA effort of these faculty. Such payment would represent dual compensation by the federal government for the same work. Faculty with a joint appointment may request only the university's share of their salary in proportion to the effort proposed to be devoted to the sponsored project. The faculty member's Health Science Center salary determines the base for computing that request.

For applications to the NIH, institutional signature on the application certifies that

1) the individual is applying as part of a joint appointment specified by a formal Memorandum of Understanding (MOU) between the Health Science Center and the VA, and
2) that there is no possibility of dual compensation for the same work, or of an actual or apparent conflict of interest regarding such work.

For this reason, each new proposal submitted having key personnel with a joint appointment will need a new MOU executed for the proposed project. The published application packet for a NIH grant proposal gives detailed instructions for documenting a joint appointment. In addition, the Health Science Center instructions for completing the MOU can be accessed at the following web site: http://research.uthscsa.edu/osp/forms_ut.shtml, Memorandum of Understanding for Faculty with Joint VA-UTHSCSA Appointments. Guidance is also given at Appendix F to this Manual.

PHS 398 Instructions: For applications under joint appointment conditions, list the number of months per year reflected in the university appointment. Identify with an asterisk and provide a full explanation about the individual's total responsibilities under the joint appointment in the Budget Justification section of the proposal. Specify the title of each appointment, the types of responsibilities (teaching, research, clinical, consulting, and administration) and the proportion of each to the total set of responsibilities. OSP provides standard wording that should be used in budget justifications to describe the joint appointment, available at http://research.uthscsa.edu/osp/forms_ut.shtml.

List the percentage of the university appointment that is to be devoted to this project.

For VA responsibilities, complete the type of appointment and percent of effort on a separate line.

Postdoctoral Salary

Postdoctoral appointments are typically made to individuals conducting research. These individuals' primary goals are to extend their own education and experience. Postdocs work primarily under the direction of a faculty member and are not considered independent researchers. Benefits should be charged at the 30% rate. Most traineeships may be supplemented with *non-federal* (institutional) funds.

NOTE

Postdoctoral trainees applying for individual fellowships or included as part of an institutional training grant should request a stipend in accordance

with the guidelines provided by the sponsoring agency. These are trainee appointments and not salaried positions. In general, fringe benefit rates are not applied. Note that while most agencies allow calculation of single-only health insurance, HSC policy does not allow for inclusion of that cost in the proposal budget.

Graduate Student Salary

Each Health Science Center has a Committee on Graduate Studies which establishes salary guidelines for graduate student salaries. Typically, a graduate student is appointed to a grant at 50% time as a Graduate Research Assistant (GRA). For those students, a 10% benefit rate should be used. In certain, limited cases, student employees with job titles other than Graduate Research Assistant might budget fringe benefits at the full staff rate of 30%.

Note

In the case of graduate students, it is important to make the distinction between work and training. Salaries are paid to graduate students for work on a research grant; those salaries are listed in the salaries and wages portion of the budget. Stipends, which are generally received for training activities, are not allowable on research grants. Stipends may only be paid on training grants and are not included in the salaries and wages portion of the project budget.

Administrative and Clerical Staff Salary

Staff members responsible for providing administrative coordination and support of a funded program are considered administrative/clerical staff. Federal costing principles (OMB Uniform Guidance) limit reimbursement for administrative and clerical staff; consequently, such costs are appropriate only when these individuals are integral to the project or activity and their related effort can be specifically identified with the project or activity. Administrative and clerical salaries must be explicitly included in the budget or have the prior written approval of the awarding agency. Examples provided by OMB that illustrate with direct charging may be appropriate are as follows:

"Individual projects requiring project-specific database management; individualized graphics or manuscript preparation; human or animal protocol/IRB preparations and/or other project-specific regulatory protocols; and multiple project-related investigator coordination and communications."

Undergraduate Student Salary

Undergraduate student salaries are proposed on a hourly rate basis consistent with the student's level of expertise and prior experience. Section 5.2.4 of the *Handbook of Operating Procedures* addresses student employment issues. Benefits for undergraduate student employees are generally calculated at 10% of wages; however, when student appointments are at 50% effort or more, the 30% benefit rate should be used.

FRINGE BENEFITS

Fringe benefits or employee benefits are treated as direct costs and should not be combined with salaries. Fringe benefits may include medical and dental insurance, retirement benefits, social security, worker's compensation, life insurance, vacation benefits, and other miscellaneous benefits. Fringe benefits are calculated as a percentage of salaries. Differing rates are used dependent on the category of employees. Appendix F, *Proposal Budgeting Information Table*, provides the rates to be used for the various categories of employees.

EQUIPMENT

Equipment is defined at the Health Science Center as any unit item with a life expectancy of one year or more and an acquisition cost of $5,000 or more. Shipping, taxes, in-transit insurance, and installation charges should be included under this category for new purchases, provided that these costs are included on the original purchase order. If an item falls outside of this definition, it is considered "expendable materials and supplies."

The equipment budget should contain an estimate and justification for all equipment needed to perform the scope of work. It is suggested that all equipment purchases should be listed on the budget by type of equipment, manufacturer's name or identifying mark, quantity, estimated cost and the basis for the estimates. Estimates should be based on catalog quotes, telephone quotes, historical costs, engineering estimates or experience. Purchasing can help to obtain vendor quotes. It is very important to document the basis for the cost estimate, as this is often requested by sponsoring agencies or must be produced in the event of a pre-award audit.

On occasion, the sponsor may request certification that the requested equipment is not already available at the Health Science Center for use on the project. OSP will provide this certification if necessary.

Note

Software is not generally defined as equipment unless it is purchased as a package with the initial equipment order and is classified as operating software essential to operate the computing equipment. Application

software is not considered equipment and should be budgeted in expendable materials and supplies.

Special Purpose vs. General Purpose Equipment

The Federal cost principles subdivide equipment into two classifications: special purpose and general purpose. Special purpose equipment is equipment that is used primarily for "research, medical, scientific, or other technical activities." As a rule, only special purpose equipment is funded in sponsored programs because it can be proven that such equipment is necessary for the goals of the project. General purpose equipment is not limited to these activities and includes equipment such as office furniture, printing and copying equipment, pagers, typewriters, copiers, word processing equipment, fax machines, and any other item one would normally find in an administrative office. General purpose equipment is unallowable as a direct charge, except where it is used primarily or exclusively for the actual conduct of the project. Therefore, the contemplated purchase of any item of general purpose equipment should be fully outlined and justified in the budget as being essential to the conduct of the project and reserved only for the use of the project.

EXPENDABLE MATERIALS AND SUPPLIES

The expendable materials and supplies category of a budget generally refers to consumable materials or supplies that will be used during the budget period. Supplies may consist of items such as: items costing less than $5,000 or with a useful life of less than one year; computer supplies; project-related consumables such as glassware and chemicals; project-related items such as books, periodicals and tapes (which are not readily available through the Library or which must be used on a daily basis for the conduct of the project), software packages, laboratory animals, and radioactive isotopes.

Supplies should be listed in the budget by type (e.g., chemicals, computer supplies, and glassware) and by estimated cost. Some sponsors will require that the basis for cost estimates be included in the budget justification; federal sponsors have restrictions on basic office supply purchases.

General office supplies are only appropriate to request as a direct cost if the cost can be justified as have a sole direct technical benefit to the project and essential to the performance of the project.

CONSULTANTS

Consultant costs are included when personnel outside the Health Science Center are needed to provide a professional service for a fixed period of time; Health Science Center employees are generally not eligible to serve as a consultant for compensation beyond their base salary. When budgeting for consultants, it should be first determined

that the person meets the Health Science Center's criteria for such consulting (see Section 7.2). Consultants should be budgeted only when on-campus expertise does not exist or is not readily available.

Consultants should be proposed by describing the individual's name, services to be rendered, number of days charged, justification for selection, and daily rate proposed. The daily rate may include fees and travel expenses, or related travel expenses that are itemized. Costs should be based on actual quotes from the consultant; sponsoring agencies normally require a curriculum vita for each consultant to be included with the proposal.

SUBAWARDS

A subaward is an agreement with a separate organizational entity outside of the Health Science Center to perform a significant portion of the proposed statement of work. Distinguishing characteristics of a subaward include performance that meets the objectives of the program and responsibility for programmatic decision making. The subawardee directs and takes full responsibilities for its portion of the project.

The following items are required in the proposal if it has a subaward component:

a) Justification of the need for the subaward in the proposal narrative, along with the defined tasks of the subawardee or a work statement for that subawardee. Should include any deliverables antipcated to arise from the project.
b) A budget at the same level of detail that is being proposed by the Health Science Center. Note that commercial subawardees may include costs such as labor overhead, general and administrative expense, cost of money and profit or fee. Some federal agencies limit or disallow profit or fee; guidance may be obtained from OSP. The PI is responsible for reviewing the subaward budget to ensure that is reasonable and consistent with the goals of the project.
c) A letter of commitment or statement of intent must be submitted with the proposal. Proposals from other organizations must include a signature of an official authorized to legally commit that organization or institution to the portion of work described and the corresponding budget.
d) A copy of the subawardee's current F&A rate negotiation agreement if F&A costs are requested. This can usually be obtained from the organization's equivalent OSP Office.

NOTE

Determination of whether someone is a consultant, whether a subaward should be issued to an individual's organization, or whether a vendor

purchase order should be issued can be obtained from the OSP. A vendor purchase order is defined as an order for normal supplies, services, or equipment.

TRAVEL

Separate detail should be provided in the budget for foreign and domestic travel. Foreign travel is any trip outside the United States, its territories, possessions, and Canada. Foreign travel usually requires special authorization from the sponsor.

The Health Science Center's *Travel Operating Procedures* should be consulted when proposing travel costs. The Health Science Center will reimburse the travel on a per diem basis; it will not reimburse travelers for costs in excess of fares as published in the *Travel Operating Procedures*.

It is suggested that each trip proposed in the budget be listed separately and include the following detail: names and numbers of travelers; point or origin and destination; cost of transportation (e.g., airfare or mileage); per diem costs for lodging and meals, incidental expenses such as ground transportation, and conference or registration fees.

It is important that the relevance of the trip to the proposed project be described in the budget justification. Expenses are reimbursed for the period of travel only and must be reasonable to the project. Entertainment expenses (e.g., movies, alcohol, and payment of guest meal expenses) are generally unallowable.

OTHER DIRECT COSTS

Other direct costs proposed for sponsored funding may include the following:

Communications

These costs include charges for postage and telephone. On federally funded projects, postage costs for routine correspondence and local telephone costs (equipment, installation, maintenance, line charges, fax lines, pagers) are generally unallowable and are only appropriate to budget if the purpose of such is for the sole direct benefit of the project. Network expenses are allowed if appropriate to the project and justified; these costs must be explicitly budgeted and specifically identified. Examples of allowable communication expenses include shipment of project materials and deliverables, express mail charges, long distance telephone charges, and fax transmission charges. A listing of such items and the estimated cost is required.

Repair and Maintenance

These costs include charges for maintenance, repair or upkeep of property utilized in the performance of the sponsored project. Budgeting should be based upon actual experience or costed in accordance with actual maintenance

agreements. Proposal detail should include a listing of the type of equipment to be maintained and the estimated cost.

Other Services
Other services include professional services by Health Science Center departments and outside firms. Internal services include those performed by Instrumentation Services, the Copy Center, and Health Science Center departments or organizations offering services to projects, such as shared institutional cores and facilities. For internal services, budgets should reflect actual quotes received from those departments based upon the current fee structure. Budgets should list the types of services required and the estimated fee.

Publication Costs
Publication costs consist of the preparing, publishing, and sharing of project findings and supporting material. Budgets should use reasonable efforts for publication and page charges. If color reproductions are required (to accurately depict the photograph, for example), explicit justification should be made.

Human Subjects Fees
Human subjects sometimes receive financial compensation for their participation in research projects or clinical trials. The number of subjects and related fee should be stated in the budget. Guidance on appropriate fees for human subjects can be obtained from the Institutional Review Board (extension 210-567-8250).

Patient Care Costs
Patient care costs may include the following: inpatient room charges, use of outpatient space, ancillary tests (e.g., laboratory, radiology), supplies used directly with patients (IV's, syringes, drugs, disposables, etc.), food provided to patients as part of special research diets. Expenses such as separately identifiable nursing and dietary salaries, equipment, and non-patient costs are anticipated in other budgetary categories. Patient care expenses are excluded from F&A costs.

Rental Space
Lease and rental expenses for non-university buildings and offices are included in this category. Budgeting should be based upon actual experience or upon the actual lease agreements. PI's requesting reimbursement for rental property should coordinate such rental facilities with their department chairs and deans in advance. Proposals should list the type of lease or rental and the estimated costs. Budgets proposing space rental may include building maintenance and upkeep, if appropriate. Rental space is excluded from F&A costs.

Alterations/Renovations or Construction

Costs of alterations or construction to a sponsored project are rare and must be fully justified and supported. PI's should discuss any proposed renovation charges with the sponsor's scientific liaison in advance. Proposals directly in response to an RFP for a facilities construction grant are generally limited in numbers that can be submitted by each institution. All such proposals are coordinated with the department and dean's offices in advance and approved proposals should also be coordinated with Facilities Management. Capital expenditures for construction, alteration and/or renovation are excluded from F&A costs.

Tuition/Fees for Graduate Research Assistants

Graduate student employees working on sponsored projects and identified as Graduate Research Assistants are eligible for their tuition and fees to be paid as part of their compensation on grants and contracts. Funds for tuition and fee expenses should be budgeted at the in-state tuition rate under the "other direct costs" category (not included within the salary). These costs may be budgeted on grants and contracts commensurate with the student's effort and salary on the project, provided the sponsor allows for such costs. If the sponsor disallows tuition costs, the student's mentor will be responsible for covering these costs from another non-grant, non-state source of funding instead. Tuition/fee expenses are excluded from F&A costs.

FACILITIES AND ADMINISTRATIVE (INDIRECT) COSTS

What are Facilities and Administrative costs? As previously discussed, Facilities and Administrative (F&A) costs (or indirect costs) are real costs that cannot be separately identified or measured for a specific project, but are shared costs with other activities. At the Health Science Center, the F&A cost rate is comprised of the following components:

Facility Components

- *Building Depreciation.* Depreciation on all Health Science Center buildings less any construction financed by federal funds;
- *Equipment Depreciation*: Depreciation on all Health Science Center-owned equipment which was not purchased with federal funds;
- *Operations and Maintenance Expense*: Utilities, maintenance and repair of Health Science Center buildings; and
- *Library*: Library operations including the purchase of books, journals, and serials, less any applicable credits.

Administrative Components

- *General Administration:* Administrative salaries and expenses of offices such as the President, the Vice Presidents, Human Resources, Purchasing, Payroll and Accounting;
- *Department Administration:* Administrative salaries and expenses of Department and Dean's offices; and
- *Sponsored Project Administration:* Expenses of Sponsored Programs, certain Accounting functions, Institutional Review Board, and related activities.

The Health Science Center develops an F&A proposal using the actual costs of a base year. The rate is based upon an analysis of indirect costs associated with all sponsored program activity for the prior year and is developed by the Office of Sponsored Programs. That rate proposal is submitted for review, negotiation, and eventual mutual agreement to the Health Science Center's cognizant federal audit agency, the Department of Health and Human Services.

Negotiated F&A Rate ✉

The Health Science Center's negotiated rates as listed in Appendix E, *Proposal Budgeting Information table.*

Explanation and Example of MTDC Base

The F&A cost rate is applied to a Modified Total Direct Cost Base, The base is comprised of most of the direct costs of a specific project; however, there are several costs that are specifically excluded from the F&A cost charge. These exclusions have also been negotiated as part of the Health Science Center's approved federal rate and match those exclusions stipulated in the federal cost principles. The exclusions are:

- Capital equipment costing $5,000 or more;
- Tuition remission, scholarships and fellowships;
- Costs of each subaward (for substantive work) in excess of the first $25,000 for the entire competitive segment;
- Rental or lease of space or equipment;
- Costs of any construction, alteration and or renovation; and
- Patient care costs.

Because the calculation of F&A costs can be confusing, the example below is provided:

Example 3-5 Computing the MTDC Base

The total direct cost proposed to the National Institutes of Health by Dr. Smith equals $335,000. This sum includes $12,000 in equipment, $20,000 in laboratory renovation costs, and a $115,000 subaward to University X.

Total Direct Costs		**$ 335,000**
Less Exclusions:		
Capital Equipment ($5,000 or more per item)	12,000	
Subaward balances over $25,000 ($115,000-$25,000)	90,000	
Laboratory renovation costs	20,000	
Subtotal Exclusions	**$ 122,000**	
Resultant MTDC Base = $213,000		
Apply the Current F&A Rate (52.5%)		**111,825**
TOTAL PROJECT COSTS (Direct Costs plus F&A)		**$ 446,825**

Off-Campus Rate
The off-campus indirect cost rate should be used when the project takes place in any facilities not owned or for which rent is not being paid from institutional funds by the Health Science Center. Typically, budgets should use only one F&A cost rate; if more than 50% of the work is being performed off-campus, the off-campus rate applies to the entire project.

Industry-Sponsored Clinical Drug Study Rate/Sponsored Research/Testing
The F&A rate assessed to clinical drug studies is 30% of total direct costs with modifying exclusions for only the IRB and advertising costs. The F&A rate of 26% must be utilized for all other non-clinical industry-sponsored agreements. For Phase I SBIR or STTR proposals, where the Health Science Center is to be a subawardee, the 26% rate is applicable; Phase II SBIR or STTR proposals should use the full, federally-negotiated rate.

Other Applications of the F&A Rate
There are a number of sponsors who, through published policy, limit payment of F&A costs. These sponsors generally include foundations, voluntary health organizations, and state agencies. There are also certain federal programs, such as training grants, which limit F&A costs. The Health Science Center will abide by the written policies and F&A limitations of these organizations and agencies. If a sponsor does not have a written policy on the payment of F&A, the full rate must be requested in the proposal unless a wavier of F&A is obtained.

It may be appropriate to propose a reduced F&A rate for non-research proposals (i.e., service or testing agreements). OSP should be consulted for the appropriate rate to be applied to these types of proposals.

Waivers of F&A (Indirect) Costs
Waiver authority of F&A is vested in the Vice President for Administration and Business Affairs. "Automatic" waivers are granted to those federal, state, and non-profit agency programs that have written guidelines on limitation of indirect cost rates, such as the 8% limitation on training grants or the American Cancer Society's limitation of 10% on all its grant programs. Information on the written policies of a sponsor's reimbursement of F&A costs can be obtained from OSP. Any waiver should be discussed with OSP as soon as possible when planning to submit a proposal. Requests for F&A waivers are initiated by the Principal Investigator/Project Director and must be endorsed by the appropriate department chair or director. The endorsed request should be sent to the Vice President & Chief Financial Officer via OSP. Information regarding the contents of the request and further information on the HSC's policy on F&A costs can be found at http://www.uthscsa.edu/hop2000/7.1.2.pdf.

3.6 Cost-Sharing

Cost Sharing Definition
The federal government defines cost sharing as "that portion of project or program costs not borne by the federal government." Cost sharing is the amount of project costs, including unreimbursed faculty effort that the Health Science Center will contribute towards a sponsored project regardless of sponsorship.

Matching Grants
Matching grants are grant programs requiring that funds awarded be matched proportionately by other sponsors or the Health Science Center. Some federal and state sponsors require matching support from non-governmental sources, such as from industry.

Proposing Cost Sharing
Caution should be used when proposing cost sharing on a sponsored program. For example, stating that a faculty member will devote 5% of his/her time to a project at no cost to the project commits the Health Science Center to tracking and accounting for that faculty member's time and, ultimately, this unreimbursed effort has a negative effect on the indirect cost rate. Other types of cost sharing, including volunteer time of those not on the Health Science Center payroll, or various supplies and services will generally require that the Health Science Center maintain auditable records of that cost sharing. Contingent on sponsor policy, the difference in indirect costs allowed by the sponsor and the Health Science Center's actual indirect cost rate may also be used as cost sharing.

Some programs require cost sharing. In those instances, individuals are urged to contact OSP for suggestions on how those obligations might be portrayed in the budget. For those programs where no cost sharing is required (most research grants, for example), individuals are urged not to volunteer such cost sharing through unreimbursed faculty effort or through other means.

When proposing cost sharing, it is also useful to be mindful of the accounting requirements for such cost sharing; see Section 6.8.

NOTE:

Funds used as cost sharing on one federal project cannot be used for cost sharing on another federal project.

3.7 Budgeting for Industry-Supported Clinical Trials

Industry-supported clinical trial budgets are computed differently than normal research or project budgets. In general, the Principal Investigator is usually presented with a per patient cost by the pharmaceutical company. A clinical study agreement may also include other fees such as special payments upon patient enrollment, etc. It is the responsibility of the Principal Investigator and the Department Chair to ascertain whether the per patient amount is adequate to cover all trial expenses. The Health Science Center assesses a 30% flat indirect cost rate on clinical trial payments. As well, the appropriate dean and department chairs can an in some cases do, at their discretion, assess additional administrative fees/indirect costs. These costs typically, but not always, do not exceed an additional fifteen (15) percent.

CHAPTER FOUR

PROPOSAL REVIEW, APPROVAL, AND PROCESSING

4.1 Review and Approval Responsibilities

Each proposal must be reviewed and approved prior to submission to the funding agency. The review and approval may vary depending upon the nature of the proposal and the extent upon which the proposed project needs additional review by Health Science Center regulatory committees (e.g., human subjects, animals, biohazards, etc.)

4.2 Certificate of Proposal (COP) ✉ 🗎

When the proposal is submitted to OSP for final review and signature, but prior to submission to the funding agency, a completed and signed *Certificate of Proposal* (http://research.uthscsa.edu/osp/forms/cop.pdf) must accompany it. The *Certificate of Proposal* represents a review of administrative, policy and fiscal issues affecting the proposal and consists of a series of information items and questions to assist the Investigator and Health Science Center reviewers in assessing potential risks and obligations which could be assumed if the proposal is funded.

Where there are faculty from more than one academic department who will participate in the proposed project, signatures of their appropriate department chairs are also required prior to OSP institutional signoff.

The COP is also required when an agreement or contract is received and no formal proposal has been submitted. OSP will also advise Investigators and administrators at all other times when the COP is required.

4.3 Other Just-In-Time Submission Approvals and Requirements

Health Science Center and funding agency policy requires certain other approvals to be in place prior to the submission of a proposal. These are also noted on the Certificate of Proposal and include:

- Institutional Review Board (IRB) Approval for Human Research. The Institutional Review Board must review all proposals using human subjects. Use of human subjects in research is defined as "*a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge…*" using "*living individual(s) about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable private information.*" (Code of Federal Regulations, Title 45, Part 46.102(d) and (f). Some sponsors will not accept pending review status; sponsor instructions should be consulted.

- Institutional Animal Care and Use Committee (IACUC) Approval for the Use of Animals in Research. The Institutional Animal Care and Use Committee must review all proposals using animals. As with human subjects, some sponsors will not accept pending review status; consequently, sponsor instructions should be carefully reviewed.

- Institutional Biohazard Committee for Replicating or Recombinant DNA Experiments. Federal regulations required approval by this Committee when research involves the use of replicating agents, radioactive drugs, or recombinant DNA, whether funding is required or not.

- Institutional Chemical Safety Subcommittee. Approval by this Committee is required when research involves the use of chemical carcinogens and extremely toxic substances.

4.4 Proposal Review

All applications for support for external funding must be reviewed by OSP prior to submission to the funding agency. OSP reviews the proposal for consistency with agency guidelines and compliance with Health Science Center policies.

In particular, the budget will be reviewed carefully to ensure the correct application of rates, proper format, and verification of any institutional cost-sharing commitments. Investigators are encouraged to submit draft copies of the budget well in advance of the

proposal due date for review, but no later than three (3) business days prior to due date of the proposals.

The Senior Director, Office of Sponsored Programs has been delegated signature authority for all proposals submitted to external sponsors by the Health Science Center.

NOTE: ITEMS NEEDED PRIOR TO OSP SIGNATURE ON A PROPOSAL:


OSP is not authorized to provide institutional sign-off without the following items:

- Completed and signed *Certificate of Proposal*

A copy of the proposal for OSP files should either be submitted at time of proposal review or within three days after submission.

*If required by sponsor at time of submission

4.5 Protection of Proposal Information

Should a PI/PD wish to protect ideas, information and data presented in a proposal against improper use by others and premature disclosure, he/she may wish to include the following or a similar general statement on the face page of the proposal:

> *"The contents of this proposal may not be disclosed to the public beyond the normal distribution necessary for proper review and evaluation for possible funding, nor used by the Government [or Sponsor] for any other purpose, without the express written approval of the Principal Investigator (or the Project Director) and an authorized official of the Health Science Center."*

Alternatively, specific portions of the proposal may be prefaced on each page containing individual salary information or proprietary scientific information or data with a legend similar to the following:

> *"Following is information that The University of Texas Health Science Center at San Antonio considers proprietary and which it requests not be released to persons outside the Government [or Sponsor] except for evaluation purposes."*

4.6 Transmitting the Proposal

In most cases, proposals are transmitted to the sponsor electronically via an online submission system. Many different systems exist and are used for this purpose, and each system varies in its capabilities and specific requirements. For example, in some cases the Principal Investigator must transmit the proposal; in other cases, transmission must be handled by the OSP. Principal Investigators are urged to work with their assigned OSP proposal reviewer to ensure everyone understands their roles and responsibilities in the submission process.

If the sponsor requires the proposal to be mailed in hard copy, the Principal Investigator/Project Director's academic department is generally responsible for making the necessary copies of the proposal and for mailing. If requested, OSP will mail the proposal upon receipt of the necessary copies (and a copy for OSP) prior to ten (10:00) a.m. of the day on which the proposal should be mailed. Costs for priority or overnight mailing will be assessed to the Principal Investigator/Project Director's academic department.

4.7 Site Visits

A site visit may be part of a sponsor's review of the proposed research. Site visits are generally made for very large and expensive projects, such as for program projects and center grant proposals. Normally, the site review team will be made up of scientific and administrative officers from or representing the sponsoring agency, occasionally a fiscal consultant, and a varying number of scientists specializing in the field with which the proposal is concerned. The site visit team generally reviews the following criteria:

- scientific merit of each component of the program and of the overall program;
- requested budget;
- use of human/animal subjects (notify the IRB or LAR of the visit as appropriate);
- contributions of subawardees and collaborators;
- administrative structure;
- resources and project environment; and
- overall strength of the Health Science Center and its commitment to the project.

The agenda for a site visit is the responsibility of the Principal Investigator/Project Director and should be submitted to the Sponsor's site visit administrative officer one month prior to the visit. This will give the administrative officer an opportunity to review the agenda, as well as to review it with the site visit chair. They may suggest revisions

based on their experience. These revisions should be accepted if at all possible. The following strategies are provided as further assistance:

Strategies
Place yourself in the site visitors' roles and remember that their task is to acquire additional information. Make it easy for them to write their reports by:

- Providing a handout at the beginning of the site visit that includes copies of all slides and materials to be used at the site visit, organized and tabulated according to the agenda. The site visitors will use these directly to write program descriptions and their critiques.
- Having all presenters available at all times throughout the site visit (in the room or on call).
- Understanding that careful and critical rehearsal of presenters is essential.
- Using an ample-sized conference room, preferably one with an oval or u-shaped table, and make sure that presentation equipment is working.
- Being prepared to follow-up on questions in writing. Do not assume that because you may have a specific comment during the site visit that it will become a part of the formal written record.

Points to be Avoided

- Do not change budget requests the night before the visit. A changed budget constitutes a new application.
- Do not call or write individual site visitors or the site visit chair before or after the site visit unless requested specifically to do so.

OSP should be contacted if a representative from that office is either necessary or could be useful in attendance at a forthcoming site visit or if you need assistance with preparations for a site visit.

4.8 Pre-Award Audits

Where a proposal submitted to a federal agency is likely to result in the award of a contract and the budget exceeds $500,000 per year, a pre-award audit maybe undertaken by the federal funding agency. This audit will occur prior to an award being issued. If an audit (often referred to as a Field Pricing Report) is required, the federal sponsor generally requests DHHS to review the proposal budget to ensure that it is adequately documented and that all rates are current.

Pre-award audits may either be conducted in person or via telephone and email by the sponsor and should be coordinated through OSP. Assistance will be needed from the PI/PD and the academic department on specific cost or pricing issues.

4.9 Unfunded Proposals

Should the principal investigator/project director receive notification from the prospective funding agency that the submitted proposal will not be funded, a copy of the notification should be sent to OSP.

CHAPTER FIVE

AWARD ACCEPTANCE AND PROJECT ID ESTABLISHMENT

5.1 Types of Awards

What is an award
An award is broadly defined as financial support for a specific research project, training program, equipment purchase, or other type of project funded by an external sponsor. The most common types of awards are grants and contracts.

Grants
Grants are normally financial assistance for basic research, training, or outreach projects, with the scope of work originating with the Principal Investigator/Project Director. Grants have general, standard terms and conditions that do not normally require negotiation by OSP.

Contracts/Agreements
Contracts provide financial support for a specific task, with the scope of work usually originating from and determined by the sponsor. Contracts have terms and conditions, specific to the award, which generally must be negotiated prior to acceptance of the contract to ensure compliance with University of Texas System and Health Science Center policy. These negotiations are conducted by OSP in consultation, when necessary, with the Principal Investigator/Project Director, the academic department, and, when necessary, the Dean, the Office of Legal Affairs, the Office of Technology and Commercialization, or other Health Science Center offices.

Other Awards

There are other types of awards such as cooperative agreements, purchase orders, ordering agreements, etc. All of these, when they meet the definition of a sponsored program as outlined in Section 1.2 have accounts established through the Office of Sponsored Programs.

Regardless of the type of award received, the Health Science Center has certain responsibilities to adhere to the terms and conditions of the award including the completion of all required reports. A discussion of those "post-award" responsibilities is found in Chapters Six and Seven.

5.2 Signature Authority

Signature authority for all sponsored program agreements has been delegated by the President to the Senior Director, Sponsored Programs and other staff members in the Office of Sponsored Programs.

5.3 Project ID Establishment

Once a proposal has been funded and an official notification of the award (Notice of Grant Award, letter of award, fully executed contract, or the like) has been received from the sponsor, OSP will assign a Project ID to the project.

Project Grant Activation Notice (PGA)
In conjunction with assigning the Project ID, OSP will produce an internal *Project Grant Activation Notice* (PGA) which indicates, in part, the Project IDs for the budget period, the F&A (indirect) cost rate, authorized signatures, percent effort of key personnel and special instructions to Accounting as well as any unusual requirements for the award. The PGA is electronically sent to the Investigator, a Department/Unit designated representative, Accounting, and, if applicable, the Department of Laboratory Animal Resources.

Project IDs will not be established unless OSP has a copy of the original proposal (if any), a current project budget, and evidence of approvals of the use of human or animal subjects, as applicable.

5.4 Advance Project IDs

Establishing Project IDs Prior to Award Receipt

Under certain conditions, an Investigator/Director or department may request a Project ID prior to the actual receipt of the award. This can be done according to sponsor guidelines and regulations through the submission of an email to OSP at grants@uthscsa.edu which requests the advance Project ID and should be sent by departmental administrator who as the ability to guarantee payment of the expenditures should the expected award not be issued.

Note:

In most cases, pre-award costs cannot be incurred more than ninety (90) days prior to the actual award start date (without sponsor approval). Prior to incurring pre-award costs, OSP should be consulted for the allowability of such expenditures.

In anticipation of receiving an award notice from the funding agency and in those instances where an award will be continuing into another budget period (such as an NIH research award with multiple budget periods), during the month preceding the expected continuation or renewal award OSP will either automatically extend the current Project ID or establish a new Project ID in order that payroll appointments may be continued.

Note:

Principal Investigators/Project Directors or other personnel involved in the administration of projects are cautioned against “parking” salary charges on an expiring award. “Parking” salary charges means placing salaries on a Project ID that is not currently or will not be the Project ID to which salaries will eventually be charged. Rather, a new Project ID, if appropriate, should be requested using the above guidelines.

CHAPTER SIX

FINANCIAL MANAGEMENT OF AWARDS

6.1 Allowable Direct Costs

Health Science Center policies regarding the allowability of costs charged directly to a project are predicated upon the requirements of the federal costing principles, OMB Circular Uniform Guidance. To be eligible as a direct cost, the charge must be allowable, allocable, and reasonable to the Project ID. Appendix I provides important guidance, by cost category, as to the allowability of certain direct costs.

6.2 Determining the Allowability, Allocability and Reasonableness of Costs

In accordance with the requirements of the Federal OMB Uniform Guidance which sets forth the cost principles educational institutions must use in incurring costs charged to federal agreements, the Health Science Center's policy of determining the allowability, allocability, and reasonableness of costs is as follows:

Determination Factors

When incurring costs against sponsored funds (i.e., making payments utilizing funds from outside agencies in support of Health Science Center projects), the academic unit administering the project is responsible for determining three factors regarding the cost prior to authorizing the cost and processing the financial paperwork. These three factors are:

Allowability of Costs
This factor determines whether the cost being considered would be authorized for payment under the terms of the award made by the sponsor. The basic question to be answered under this factor is "Will the sponsor pay for this expense?"

- The tests of allowability of costs are:

1. they must be *reasonable*;
2. they must be *allocable* to sponsored projects under the principles and methods provided herein
3. they must be given *consistent* treatment appropriate to the circumstances and must comply with the Health Science Center's Cost Accounting Standards Disclosure Statement; and
4. they must conform to any limitations or exclusions set forth in OMB Uniform Guidance, the award document, or the agency's guidelines as to the types or amounts of cost items.

Allocability of Costs

A cost is allocable to a particular cost objective (i.e., a specific function, project, department or the like) if the goods or services involved are chargeable or assignable to the cost objective in accordance with the relative benefits received or other equitable relationship. The basic question of allocability is "Is the expense related to the project?"

- Subject to the foregoing, a cost is allocable to a sponsored project if:

1. it is incurred solely to advance the work under the sponsored project;
2. it benefits both the sponsored project and other work of the Health Science Center, in proportions that can be approximated through using reasonable methods; or
3. it is necessary to the overall operation of the Health Science Center and, in light of the principles provided in OMB Uniform Guidance, is deemed to be assignable in part to sponsored projects.

Where the purchase of equipment or other capital items is specifically authorized under a sponsored project, the amounts thus authorized for such purchases are assignable to the sponsored project regardless of the use that may be subsequently be made of the equipment or other capital items involved.

NOTE

Any costs allocable to a particular sponsored project under the standards provided herein may not be shifted to other sponsored projects in order to meet deficiencies caused by overruns or other funding considerations, to avoid restrictions imposed by law or by terms of the sponsored project, or for other reasons of convenience. In addition, any costs allocable to activities sponsored by industry, foreign governments, or other sponsors may not be shifted to federally sponsored projects.

Reasonableness of Costs

A cost may be considered reasonable if the nature of the goods or services acquired or applied, and the amount of funds involved reflects the action that a prudent person would have taken under the circumstances prevailing at the time the decision to incur the cost was made. In other words, "Is the expense reasonable?"

- Considerations involved in the determination of the reasonableness of a cost are:
    1. whether or not the cost is a type generally recognized as necessary for the operation of the Health Science Center or the performance of a sponsored project;
    2. the restraints or requirements imposed by such factors as Federal and State laws and regulations, sponsored agreement terms and conditions, or agency guidelines;
    3. whether or not the individuals concerned acted with due prudence in the circumstances, considering their responsibilities to the Health Science Center, its employees, its students, the Government, and the public at large; and
    4. the extent to which the actions taken with respect to the incurrence of the cost are consistent with established Health Science Center policies and practices applicable to the work of the Health Science Center generally, including sponsored projects.

Review Strategy / Documents

In determining the above, the following documents should be reviewed:

Approved Project Budget
The allowability of a cost is first determined by examining the budget that the agency approved for the project. Does the proposed expense show up under a line of the budget? If the item does not appear on the budget, then other reviews must be conducted to determine if the charge is allowable under a rebudgeting authority that may be granted to the Health Science Center, or if the item may be allowable only if prior approval is obtained in writing from the agency. If the budget has not been incorporated into the award document, then allowability must be determined in accordance with allowable cost principles of the agreement (OMB Uniform Guidance).

The Award Document or Contract
Allowability of certain costs may be addressed within the award document or the contract/agreement that was issued for the sponsored project. For example,

grant awards may identify certain costs that are specifically unallowed by the agency based upon recommendations from the peer review system.

Agency Guidelines
Even if the type of expenses proposed appear on the budget, the specific expense may not be allowable. Most Federal agencies have guidelines for administering grants. These guidelines give direction on the allowability of certain costs. For example, travel costs may appear in the budget, but a specific trip taken to a foreign country may require further approval from an agency pursuant to their guidelines.

OMB Uniform Guidance
The primary governing regulations for determining the reasonableness, allocability, and allowability of costs on Federal awards, in addition to all other sponsored projects, is the Office of Management and Budget Uniform Administrative Requirements, Cost Principals and Audit Requirements for Federal Awards (OMB Uniform Guidance). Subpart E – Cost Principals Selected Items of Costs Sections 200.420 – 475 identifies the allowability of costs

6.3 Rebudgeting

Sponsors have differing policies for the rebudgeting of funds. Some sponsors allow latitude in making budget revisions and most requests for budget revisions can be handled at the Health Science Center level. OSP staff can help to determine whether an award agreement and sponsor policies permit reallocation among budget categories. A written request to the sponsor, countersigned by OSP, may be required. Any rebudgeting request must detail how this request will benefit the statement of work or specific aims.

6.4 Carryforward of Funds

Carryforward of funds from one budget period to the next is dependent upon the funding agency's policy. When such carryforward is allowed, it generally must be less than 25% of the previous period's total budget unless approved by the sponsor.

6.5 Transfers of Costs

It is the responsibility of the Principal Investigator/Project Director and his or her administering unit to ensure that only allowable and allocable costs are expensed against a Project ID. After the fact transfers of costs onto federal projects should be minimized. Examples of after the fact cost transfers include: transfer pre-award costs from a departmental (non-federal) project/grant, correction of clerical errors, reallocation of salary costs to reflect actual expended effort, routine allocation of shared services, and service center charges.

Frequent (not less than monthly) monitoring of project/grant ledgers should be made to assure that all charges have been applied correctly. If errors are made, they should be corrected promptly and procedures implemented that minimize future occurrences.

To comply with the cost allowability and allocability requirements of federal cost regulations it is necessary to explain, justify, and document transfers of charges into federal awards from other federal or non-federal projects.

The full cost transfer policy is available at http://uthscsa.edu/hop2000/7.1.5.pdf.

6.6 Documentation of Compensation on Sponsored Programs

The Health Science Center is required by the federal government to review and certify to the time and effort spent by employees on sponsored programs. This is done through the onlinee Effort Certification System. This system reflects an individual's payroll distribution to various institutional Project IDs, including sponsored programs, and their estimation of actual time spent on activities such as instruction, research, and other functions. Certification is required twice a year for faculty and staff. The certification is made through the ECRT system on both sponsored and non-sponsored projects.

The full policy is available at http://uthscsa.edu/hop2000/7.1.3.pdf.

6.7 Accounting for Program Income

Program income is defined by the federal government as gross income earned by the Health Science Center which is directly generated by a supported activity or earned as a result of the award. Program income includes, but is not limited to, income from fees for services performed, the use or rental of real or personal property acquired under federally funded projects, the sale of commodities or items fabricated under an award, and interest on loans made with award funds.

Except as provided below, program income earned during the project period shall be retained by the Health Science Center, and in accordance with federal awarding agency regulations or the specific terms and conditions of the award, shall be used in one or more of the ways listed in the following:

a) Added to funds committed to the project by the federal awarding agency and used to further eligible project or program objectives;
b) Used to finance the non-federal share of the project or program; or
c) Deducted from the total project or program cost.

Program income earned outside of the funded project period does not need to be accounted for nor reported to the federal agency. As well, royalties and license fees from copyrights or patents developed with federal funding is excluded from any reporting requirements as program income.

It is the responsibility of the Principal Investigator/Project Director to track, document, and report program income. In most cases, this reporting is made at the time of a continuation or renewal proposal for the existing project. The OSP staff can assist the Investigator in making a determination as to whether income meets the definition of program income.

The full program income policy is available at http://uthscsa.edu/hop2000/7.1.8.pdf.

6.8 Accounting for Cost Sharing

Cost sharing can be either mandatory (stipulated as a condition of the agreement) or voluntary (discretionary use of matching funds from gifts, departmental funds, etc.). Proper accounting for cost sharing is necessary not only to fulfill the terms of the sponsored agreement where the cost sharing is a requirement, but also to document for inclusion in the calculation of the Health Science Center's indirect cost rate.

The federal regulation OMB Uniform Guidance, Subpart D §75.306 permits all contributions that further the program objectives to be used for meeting cost sharing or matching requirements when the costs are:

a) Verifiable from the records of the institution;
b) Not used as cost sharing or matching on another federal project;
c) Necessary and reasonable for the conduct of the project;
d) Allowable under the applicable cost principles;
e) Not funded by the federal government (except where provided by statute;
f) Included in the program budget when required by the sponsoring agency

OSP staff review all sponsored agreement budgets to identify those that include effort (salaries) budgeted but not funded. This cost shared effort is accumulated and reported in the Effort Certification System (See Section 6.5). OSP staff will advise the Investigator and academic department staff when there are cost sharing requirements other than effort that must be documented. It is the responsibility of the Investigator and the academic department to maintain records on cost shared items other than effort including actual costs contributed and documentation for such costs not only for inclusion in financial reports submitted to sponsors, but for eventual accumulation in the Health Science Center's F&A (indirect) cost rate proposal. Such costs and documentation must be available upon request by OSP.

Unrecovered indirect costs may be used to meet cost sharing or matching requirement only when the specific sponsoring agency allows such use. When unrecovered indirect costs are used as cost sharing, OSP will be responsible for accumulating those costs.

The full policy is available at http://uthscsa.edu/hop2000/7.1.6.pdf.

6.9 Billing and Financial Reporting

The majority of billing and financial reporting for sponsored programs agreements that are lodged in the 41xxx – 44xxx fund groups are handled by the Offices of Accounting (billing) and OSP (financial reporting). There are awards, however, in which both billing and financial reporting responsibility is vested in the individual department or unit. Examples of these instances include billing on a per unit basis (such as samples analyzed), clinical drug studies where billing is done on a per patient or procedure basis, or when the billing is complex and requires detailed expenditure information. This is also true in the case of financial reporting. The Project/Grant Activation Notice (PGA) stipulates which office or department is responsible for billing and financial reporting.

CHAPTER SEVEN

NON-FINANCIAL MANAGEMENT OF AWARDS

7.1 Post-Award Changes and Approvals

Any revisions to the performance of a project that require sponsor approval must be coordinated through and endorsed by OSP. In general, the following revisions require sponsor approval:

1. Change in the Statement of Work or project objectives;
2. Increase in the amount of funds budgeted;
3. Changes in the status of the PI, key personnel, or the addition of other subawardees working on the project;
4. Changes in the budget that does not fall within rebudgeting authority prescribed by the sponsor;
5. Change in period of performance.

Requests to modify an award are coordinated through OSP for sponsor approval. Normally, sponsor approvals are handled by sending a letter that details the need and justification for the change. This letter is written by the Principal Investigator/Project Director and countersigned by OSP.

As addressed in the rebudgeting section at Section 6.3, sponsors have differing administrative policies and OSP should be consulted when considering a revision to a sponsored program.

No-Cost Extensions
The expiration date of a grant or contract may usually be extended if additional time is needed to assure successful completion of the project. This is referred to as a no-cost extension. The project's budget period normally may be extended, when justified, for up to twelve (12) months beyond the ending date of the budget period as shown on the award notice, but this is dependent on the sponsor's policies. Extensions are generally made without additional funds.

Some federal sponsors have delegated authority to the Health Science Center to approve a one-time no-cost extension of up to twelve (12) months on grants. For these sponsors, the Principal Investigator must notify OSP of the necessity of the no-cost extension, including the time needed and a project-specific justification of the extension. It is OSP's responsibility to notify the sponsoring agency and to make internal

adjustments to the award. Extension requests of this type should be made to OSP no later than thirty (30) days prior to the project's termination.

Written requests for no-cost extension (for those agencies and awards where the Health Science Center has no delegated authority) must generally be made at least sixty (60) days before the end of the currently active budget period. Written requests should be generated by the Investigator and should include the reason why the extension is needed; the month, date and year that the Investigator expects to complete the work; and the amount of residual funds and how they will be used during the no-cost extension. Many extensions may be requested electronically; please contact OSP for information on specific awards.

Change in Principal Investigator/Project Director
As a general rule, if a Principal Investigator/Project Director is absent from a project for a period three (3) months or more, a substitute PI must be proposed and approved by the sponsor. The PI must notify OSP and the sponsor's program officer at least thirty (30) days before departure or as soon as the expected absence is known.

Requests for change in PI should include a justification for the change, the curriculum vitae of the new proposed PI and any budget changes resulting from the change (such as differences in salary). The new proposed PI must also endorse the request as well as OSP.

Purchasing Procedures
Purchase of goods and services for sponsored projects must comply with both the Health Science Center policies and sponsor restrictions. Purchasing procedures as outlined in the *Handbook of Operating Procedures* should be followed in making purchases for sponsored programs just as for any other procurement. In addition, particular conditions of the award must be consulted. Some awards prohibit certain purchases, others may require advance approval of the sponsor. Advice on these restrictions is available from OSP. The allowability and allocability of any purchases made from sponsored funds and the time period of the award for which purchases are made and charged to the project should be considered. Any purchase of equipment or supplies must be made and charged within the period of the agreement. Purchases should be allocated to the appropriate sponsored project. If more than one award funds a research laboratory and the item will be used by one or more projects, the expense should be appropriately charged to each project.

Purchases Near to Termination Date
Items not received during the project period are not considered of benefit to the project and may be disallowed. Consequently, no purchase of equipment should be made later than sixty (60) days prior to the final termination date of an agreement.

Note that the government requires reimbursement for the cost of any supplies whose aggregate value exceeds $5,000 at the end of a project period. Good judgement should be used in order that supplies are purchased in quantities that can be consumed during the project period.

Equipment Purchases
The definition of equipment at the Health Science Center is an item having an acquisition cost in excess of $5,000 and a useful life of one year or more. Ideally, all equipment purchases are itemized and approved in the original proposal. Prior approval may be needed from the sponsor to buy equipment not previously authorized. As a rule, general purpose equipment such as computers or furniture will not be approved unless those items are used primarily or exclusively for the actual conduct of the program. Any requisition requesting general purpose equipment not itemized in the approved budget must include a justification from the Investigator. This justification must be retained in the academic department's records.

7.2 Purchasing Outside Services

Consultants
Investigators wishing to engage an independent consultant should first complete both a *Prior Approval Form* which outlines the terms of the consulting engagement and an accompanying *Employee/Independent Contractor Classification Checklist*. The *Handbook of Operating Procedures* outlines both the procedures for engaging outside consultants and for compensating them for their services. When hiring an external consultant, the Principal Investigator should be mindful of the following tests that determine the appropriateness of such a consultant:

- That the consultant is doing work independently without supervision;
- That the consultant has not been an employee of the Health Science Center within the last 12 months;
- That the consultant is using his/her own facilities or equipment to conduct the work; and
- That the consultant is not included on the list of excluded, suspended, or otherwise ineligible for participation in federal programs.

Subawards
A subawardee on a sponsored project is normally defined as a third party contracted to conduct a significant portion of the scope of work or research plan included in the proposal submitted to and approved by the agency for funding. As such, use of a subawardee must be integral to the completion of the workscope. When a subaward is not contemplated in the proposal, approval is generally needed in order that a subaward may be issued.

Note

A subaward issued from OSP is normally for substantive work (e.g., the subawardee is responsible for programmatic decision making and its performance is measured against meeting the objectives of the project). A purchase order for services issued by Purchasing is normally for vendor services (e.g., the vendor is providing goods and services within their normal business operations). OSP and Purchasing can provide assistance on making the determination between a subawardee and a vendor.

With sponsor approval, either through the proposal or subsequent approval, OSP will issue a subaward document that will include a scope of work and budget and incorporate the appropriate terms and conditions of the prime grant or contract. When the subawardee has agreed to the terms and conditions and signed the agreement, it can invoice the Health Science Center for its incurred expenses. Only in unusual circumstances will the Health Science Center advance funds to a subawardee. It is the Principal Investigator's responsibility to monitor the activities of the subawardee, to verify invoices submitted for payment, to verify that all deliverables have been met, and to inform the prime sponsor and OSP if significant changes are contemplated in the subawardee arrangement.

7.3 Other Award Management Considerations

Human Subjects Payments
Because of special IRS considerations inherent in payment of human subjects and for preservation of the confidentiality of the subjects, please contact the Institutional Review Board prior to initiating payments.

Travel
The Health Science Center's travel policies are detailed in the *Travel Operating Procedures*. These travel policies and procedures apply to travel on sponsored program accounts unless the sponsor's policies are more restrictive. To be allowable, travel must directly benefit the project. The terms and conditions of the award will specify whether sponsor approval in advance (and in addition to approval on the approved budget) is required.

Foreign Travel
Foreign travel may require specific approval for each trip. When using federal funds, American flag carrier restrictions will normally apply. Please consult OSP if foreign travel restrictions are unclear.

Property Management
Sponsors normally require that property purchased under sponsored agreements be used exclusively or primarily for the use of the sponsored project. Sponsors also differ in their vesting of title or reporting requirements. Some equipment acquired under a sponsored program will remain the property of the sponsor and should be managed accordingly. The Property Control Office (within the Office of Accounting) is responsible for the Health Science Center's equipment management system, including inventory, record keeping, sharing, audit, and disposition. Questions regarding property management should be directed to the Property Control Office.

Vesting of Equipment Title
In general and on most federal agreements, the Health Science Center is directly accountable for each item of equipment at the project termination. Under most federal grants, equipment is vested with the Health Science Center, the only exception being that certain agencies reserve the right to transfer the equipment following completion of the grant. This right is reserved to accommodate instances where the PI relocates to another institution and the Health Science Center has no further need for the equipment (see Section 7.5).

Surplus Property
It is expected that Investigators will not purchase equipment for use on sponsored projects that is already readily available, consistent with the needs of the project, at the Health Science Center. The Investigator should assure him or herself that any equipment to be purchased is needed by the project and cannot be shared with other investigators.

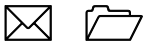
Transfer or Disposition of Equipment
There are numerous regulations regarding the transfer or disposition of property. These regulations vary under differing circumstances of ownership (title), original cost, source of funds, and current market value. For information regarding the transfer or disposition of equipment, contact either Sponsored Programs or the Property Control Office.

Intellectual Property
If at any time during the course of a sponsored project it is determined that there may be a potentially patentable invention or discovery, it is important to contact the Office of Technology Commercialization (OTC). Generally, an invention disclosure is submitted to and reviewed by the OTC in accordance with Health Science Center policies and an ultimate decision is made with respect to pursuing patenting and licensing. Many sponsored program agreements required the submission of an invention disclosure report within a relatively short time frame. OTC is responsible for submitting any disclosure or other periodic invention reporting required to the sponsor.

A copy of the Health Science Center's intellectual property policy is available in online at **http://uthscsa.edu/hop2000/12.1.1.pdf**. Questions that arise with respect to intellectual

property developed during the course of a sponsored agreement should be directed to OTC.

Publications
Investigators are expected to publish results of their research and scholarly activities. This right should be retained in all sponsored agreements. Credit should normally be given to the source of support of the project through an appropriate footnote; however, specific instructions in each grant, contract, or other agreement will govern. Under federal grants and contracts, all reports or papers submitted for publication should also contain this statement: *"Reproduction in whole or in part is permitted for any purpose of the United States Government."* Some sponsors require prior or simultaneous submission of papers or abstracts to the sponsor for review and comment; the award document should be consulted for specific requirements.

Research Data 
Principal Investigators and Project Directors should be familiar with the Health Science Center and faculty obligations and responsibilities regarding Access to and Retention of Research Data which can be found at Appendix J.

Freedom of Information
In addition to certain State of Texas statutes guaranteeing the right of access to information about public agencies, the federal Freedom of Information Act (FOIA) is applicable to federally funded projects. With limited exceptions, Health Science Center records such as policy documents and funded research proposals must be disclosed to the public upon request. There are only certain exceptions such as proprietary data or confidential salary information that can be withheld from disclosure.

Normally, FOIA requests are directed from federal agencies to Sponsored Programs. OSP will contact the Principal Investigator to inform him or her of the request and to ascertain whether there is any proprietary information that should be withheld. OSP, as a standard practice, will request deletion of any budgetary information prior to release.

7.4 Reporting Responsibility 

Financial reports, management reports, reports of findings or progress, case report forms (for clinical trials), and invention disclosures are of primary interest to any sponsor. Most formal agreements will specify the type, form and frequency of reports. The Principal Investigator is solely responsible for meeting technical and all other programmatic reporting. OSP is generally responsible for submitting financial reports using the Health Science Center's standard accounting systems, reports, and forms. When reports of expenditures are combined with requests for reimbursement, the Office of Accounting generally takes responsibility for the combined reports. In some cases with unusual financial reporting requirements, the department or particular program has

the responsibility for submitting financial reports; in those cases, the Project/Grant Activation Notice (PGA) clearly indicates this special requirement.

Delinquent Reporting
Failure to submit reports in a complete and timely manner can delay payment for final project expenses and favorable consideration of pending proposals. Some sponsors will not only withhold future awards to individual delinquent faculty, but also to any other Health Science Center faculty member anticipating funding from that same sponsor.

> **IMPORTANT**
>
> The Health Science Center considers timely reporting essential to the proper stewardship of sponsored funds. Therefore, OSP, upon consultation with the appropriate Department Chair and Dean, may withhold sign off on any new proposals for faculty who are seriously delinquent in their technical reporting responsibilities.

Close-out
OSP is responsible for assisting Principal Investigators/Project Directors with closing a sponsored project by ensuring the timely submission of required final reports. Sponsors will differ in the types of reports that may be required at closeout. Most federal sponsors will require financial, invention and technical reports. Sometimes property reports are also required. Generally, these reports are due thirty (30) to ninety (90) days from the expiration date shown on the sponsored agreement.

Final Technical Reports
Some sponsors require use of their own forms for final technical reports. These forms are available either in the sponsor's application packages, with the award documents, or on-line via the internet. Follow the sponsor's instructions for the preparation of final technical reports, which normally include a list of publications resulting from the sponsored project.

> **IMPORTANT**
>
> A copy of the face page of the final report or its transmittal letter should be forwarded to OSP for its records.

Final Invention Report
OSP will send copies of the appropriate final invention report or a certification form to the PI/PD. The PI/PD must complete and return the form to OSP who will then transmit it to the sponsoring agency.

Final Financial Reports

In general, the Office of OSP prepares final financial reports. Such reports will be submitted to the principal investigator/project director or academic department in draft form for review and comment prior to their submission to the funding agency; an exception to this policy is made in the case of federal financial reports. Expenditures against terminating accounts should be processed as early as possible and arrangements should be made to move personnel and other on-going charges to another appropriate account.

There are some instances where a particular department or program is responsible for preparation of the final financial report. Those instances will be noted on the Project/Grant Activation Notice (PGA). Final financial reports prepared at the department or program level should be submitted to OSP for review and signature prior to their submission to the funding agency.

Final Property Reports

The OSP will coordinate with the Property Control Office preparation and submission of property reports required by the sponsor. If title to property acquired under a sponsored agreement vests with the sponsor at time of completion and the Principal Investigator/Project Director wishes to have the title transferred to the Health Science Center, a request should be made to the OSP who will prepare the necessary request to the funding agency.

Close-Out Audit

Some sponsors may ask the DHHS or its auditors to perform a closeout audit before any final payment of a contract or grant is made or before the sponsor administratively closes it. If a sponsor who would like to perform a closeout audit contacts the PI/PD, please contact OSP who will then notify Internal Audit.

Deficits and Surplus Balances Upon Account Closeout

When projects are ended and all reports have been submitted, it is not uncommon for there to be a positive or negative balance in the Project ID. Disposition of those balances will be made as follows:

Deficit Balances

Sponsored projects should be administered in a manner that avoids deficit balances. Rarely do sponsors allow a transfer of a deficit balance to a new project period. Under very unusual circumstances, and with adequate justification, some agencies will allow institutions to transfer a deficit balance from one budget period to the next, within the project period only. In these situations, the estimated deficit carry forward must be stated in the progress report or continuation application.

Deficit balances should be resolved as soon as possible after the project period ends. These balances are the responsibility of the project director and his or her department and should be written off to non-sponsored program Project IDs. Deficit balances cannot be transferred to Project IDs funded with state appropriations.

NOTE:

The transfer of individual costs from one sponsored project fund group to another where the sole purpose is to offset over-expenditures is unallowable. Transfers can only be made when the charge clearly is allocable to the new account and within the limits of the cost transfer policy (see Section 6.5).

Surplus Balances

There may be cases when positive Project ID balances may be retained by the Health Science Center at the end of a project. If agency and agreements regulations allow such retention, OSP will work with the academic department in determining a Project ID to which the surplus balance may be transferred. If the surplus balance results from a fixed fee contract or agreement, the Handbook of Operating Procedures (HOP) *Section 7.1.9, Residual Funds on Fixed Fee Contracts/Agreements* should be consulted.

7.5 Record Retention

Federal regulations require awardees to prepare, maintain, and keep adequate records of sponsored project activities. Non-federal sponsors, especially pharmaceutical companies, are also very specific with respect to the retention of study records. These requirements are generally incorporated into the Health Science Center's Records Retention Schedule.

Original ledger sheets, purchase orders, invoices, payroll records and other official documents are retained by central Health Science Center administrative offices. Departments must retain original copies of budget documentation, expenditure statements signed by the Principal Investigator/Project Director, personnel files, Project ID reconciliation, and all other source documents and invoices that are used to charge costs on a grant or contract for a period of at least three years following final close-out of a grant and six years following final closeout of a contract.

For information about retention of technical data, see Appendix J.

7.6 Relocation of Investigators to Other Institutions

If the PI/PD moves to another institution, the award may be transferred as well, pending approval from the department chair, the new institution, and the sponsor. Generally, while an award does transfer with the PI/PD, criteria for this decision include considerations such as time left on the project, remaining funds, and whether the new institution has adequate facilities, equipment, and/or staff.

Transfer of equipment purchased with agreement funds in which the faculty member served as the primary investigator may be authorized under the following conditions:

1. It must be established that the equipment was brought to the Health Science Center or that the equipment was purchased from grant funds for which the faculty member was listed as the principal investigator.
2. The awarding agency that provided the funds must agree to the transfer, either through its published policies or by specific written approval.
3. The faculty member must be relocating to another educational institution that will accept title to the equipment and pay the shipping charges involved.
4. The department chair or dean certifies that the loss of the equipment will not jeopardize the research or scholarly activities of other members of the department and that funds for replacement of the equipment will not be requested if the transfer is authorized.

Health Science Center property disposition procedures must be followed on any equipment which is transferred to another institution. In general, requests for transfer of equipment to another institution are routed by an principal investigator/project director through his or her chair, OSP, and the Executive Vice President for Business Affairs and Chief Financial Officer who gives final approval of the transfer. The approved request is then routed to Property Control.

CHAPTER EIGHT

OTHER AWARDS AND AGREEMENTS

Various types of non-federal awards/agreements are made to the Health Science Center and special considerations are inherent in the acceptance of these awards. All awards, as discussed elsewhere in this Manual, must adhere to the basic policy considerations of the Health Science Center, such as the ability to freely publish results.

8.1 Industry Sponsored Agreements

It is the policy of the Health Science Center to encourage interactions and research with the private sector. Such interactions are essential to the vitality of the Health Science Center and this activity is recognized as an integral part of the Health Science Center's mission and goals.

Research supported by industry should not commence prior to the execution of an agreement outlining each party's responsibilities. This agreement should contain basic understandings such as the agreed-upon statement of work, agreement on the Health Science Center's ability to publish (which may only be subject to review and comment by the sponsor), and the ownership of intellectual property. While it is the responsibility of OSP to negotiate the terms and conditions of these agreements, Principal Investigators/Project Directors should be familiar with the policies of the Health Science Center in order to convey these accurately to a potential sponsor. This will permit all parties to have a clear understanding of the proposed research project and will allow negotiations to proceed smoothly.

The following considerations are important in dealing with industry sponsors:

Statement of Work
The statement of work should be in sufficient detail that allows both parties a clear understanding of the research project and the expected deliverables (e.g., the technical reports or a prototype). Allowances should be made for changes in research direction by the PI/PD. Should the statement of work change significantly, a provision should be made for a cost adjustment.

Time Period and Cost
A fixed period for the agreement should be stated with mechanisms for extension or renewal of the project. Full costs of the research should be paid by the sponsoring industry, including recovery of F&A (indirect) costs at the Health Science Center's corporate research rate.

Conflict of Interest
Consideration should be given as to existing or potential conflicts of interest between the investigator, the Health Science Center, and the sponsoring organization.

Warranties and Guarantees
The Health Science Center conducts research programs using best and reasonable efforts, consistent with good scientific practices. As a result, it does not guarantee or warrant research products.

Termination
Conditions of mutual termination, such as the departure of a PI/PD or unforeseen circumstances, should be stated.

Endorsement of Research Results
Because the Health Science Center imposes no limitations on the freedom of the faculty in the choice of fields of inquiry or the media of public dissemination of the results obtained, any results obtained or disseminated are the sole responsibility of the PI/PD and do not carry institutional endorsement of the Health Science Center. Consequently, the Health Science Center does not permit the use of its name in advertising or promotional material related to the results of sponsored projects.

Sample Sponsored Research Agreement ✉
When the above considerations are used as guidelines, the final agreement should be one that is mutually beneficial to the Health Science Center and the sponsor. A sample research agreement, which may be sent to prospective sponsors, is included in this Manual as Appendix K.

8.2 Agreements With Foreign Sponsors

On occasion, the Health Science Center enters into agreements with foreign governments, agencies, or corporations for the support of research and other sponsored programs. Agreements with foreign sponsors are treated identically to agreements with U.S. federal agencies, for-profit entities, and non-profit organizations.

8.3 Clinical Drug and Investigational Studies

As stated elsewhere in this Manual, clinical trial agreements are broadly defined as the testing of a drug or device on a human subject. Because clinical trials are a form of industry sponsored agreement, the considerations listed above in Section 8.2 apply to clinical trial agreements. In addition, the following other matters deserve specific attention.

Indemnification
Clinical trials are prone to legal action by third parties claiming to be harmed directly or indirectly by the research protocol. Both the investigator and the Health Science Center could be parties to a lawsuit emanating from clinical research. Therefore, it is important that clinical research is not undertaken until the Health Science Center and the sponsor enter into a clinical trial agreement which includes an appropriate liability/indemnification clause.

Payment for Injuries
In addition to an indemnification clause, the sponsor is expected to pay for any injuries to subjects that are the direct result of the study.

Confidentiality of Patient Records
Sponsors of clinical trials often require that records be provided that indicate the effects of drug intervention on patients involved in a study. It is the policy of the Health Science Center and its affiliated hospitals to maintain the confidentiality of patient records. The terms of the clinical trial make a distinction between research records, study records and patient records, the latter being strictly confidential.

Invoicing and payment on clinical drug and investigational studies are the responsibility of the investigator and/or the investigator's department or academic unit.

Sample Clinical Study Agreement ✉
A sample clinical study agreement is provided as Appendix L. Faculty are encouraged to contact OSP as soon as feasible to allow contract negotiation to take place in a timely manner.

8.4 Testing Agreements

Testing agreements are broadly defined as the conduct of a specific procedure on specific material supplied by the sponsor. An example of a testing agreement is the testing of a sponsor-furnished compound using Health Science Center-owned equipment. Acceptance of any testing agreements by the Health Science Center is contingent upon the agreement by the PI/PD, Chair, and Dean that the project is in accordance with the missions of the Health Science Center and that it contributes to the objectives of the Department and the School. Such acceptance would be through the approval signatures on the *Certificate of Proposal* (see Section 4.3). Other considerations of testing agreements are as follows:

Publication
While the data resulting from a testing agreement is often linked with the sponsor's materials (which may or may not be proprietary to the sponsor), the agreement should provide for publication by the Health Science Center of overall results or methods.

F&A Costs
All testing agreements should include F&A at a rate of 26% of total direct costs.

Financial Considerations
Payment for testing or analysis performed on a piece of equipment purchased with federal funding may be accountable as program income to the federal award. In addition, faculty members are cautioned that any testing arrangement must be competitive with costs assessed by commercial organizations for comparable work, and that any inappropriate use of testing agreements may be subject to unrelated business income tax.

Sample Lab Testing Agreement 
A sample lab testing agreement is provided as Appendix M. Faculty are encouraged to contact OSP as soon as feasible to allow contract negotiation to take place in a timely manner.

8.5 Equipment Loan Agreements

Equipment loans are agreements whereby a sponsor loans certain equipment to the Health Science Center, such as hardware, software and/or documentation for research use. One such example is an agreement whereby the Health Science Center and the company participate in a joint research program using the company's equipment, and share the results, including data. This type of agreement usually does not involve

money, but enables the Health Science Center and industry researchers the opportunity to use each other's facilities. This type of agreement may involve both OSP and Purchasing to ensure that the terms are consistent with those typically negotiated with an equipment vendor and places the Health Science Center in a position of minimal risk and liability. Other considerations of these equipment loan agreements are the eventual disposition of the loaned equipment, the cost of equipment maintenance, and possible confidentiality of equipment specifications or performance.

8.6 Material Transfer Agreements

Material Transfer Agreements (MTA's) are contracts in which tangible research property or unique research resources, such as biological organisms or computer software, are provided by external sources to Health Science Center investigators for research purposes, or vice versa. Some standard considerations of MTA's are:

1. Substances are generally biological materials that are not used on human subjects and do not involve liability to the donor for the recipient's use of the material;

2. The recipient generally agrees to give intellectual property rights, such as licenses, to the donor, or limited rights if derivative materials are later developed;

3. Unused materials are returned to the donor;

4. A report of research results is generally the deliverable in exchange for the use of the materials; and

5. The donor may charge the recipient for costs of producing and shipping the material.

The Office of Sponsored Programs handles incoming MTA agreements as well as those outgoing to a non-profit recipient. Outgoing MTA's to a for-profit recipient are handled exclusively by the Office of Technology Commercialization. Please refer to the OSP website for processing instructions and forms.

8.7 Intergovernmental Personnel Act Agreements

Intergovernmental Personnel Act Agreements (IPAA) are contracts wherein a Health Science Center employee may serve or cross-train in federal agencies for limited, defined periods of time. While some or all of their salary and staff benefits are paid by the federal agency under Title IV of the Federal Intergovernmental Personnel Act, they

are still considered Health Science Center employees. Normally, provisions have been made for their return to the Health Science Center. Faculty or staff contemplating an assignment under an IPA must consult with the appropriate chair or dean. They will review the appropriateness of the arrangement and the impact upon the Health Science Center. IPAA agreements are handled through the Office of Sponsored Programs; separate Project IDs will be established for each agreement.

8.8 Clinical Services Agreements

Various departments of the Health Science Center provide clinical or patient care services to area agencies or hospitals. Such agreements are processed through the Office of Sponsored Programs and require the same approvals as those of all other types of sponsored agreements. Generally, however, these expenses incurred under these agreements are handled by MSRDP and Project IDs are established within the MSRDP fund series.

CHAPTER NINE

RESEARCH REGULATION

In addition or as a supplement to regulations already noted in this Handbook, listed below are important regulations or policies of Federal sponsors and the Health Science Center.

9.1 Human Subjects

All human subjects research must be approved by the Institutional Review Board (IRB) prior to implementation. Human research is the use of any information about or obtained from living persons. This broad definition encompasses a wide variety of activities such as in vivo and in vitro studies, review of medical records, collection of data through surveys or observation, performance of blood tests, examination of pathological specimens, discarded tissue or secretions, any use of investigational drugs or devices, and randomized trials. Research, in the context of human subjects use, is defined as a systematic investigation, including research development testing and evaluation, designed to develop or to contribute to generalizable knowledge.

Because all human subjects research must be approved by the IRB, if there is any doubt as to whether IRB review is necessary, the IRB office should be contacted to make the determination. *Prior to writing his/her first proposal,* every prospective Investigator should familiarize him or herself with the issues related to human research and with the process by which IRB approval is obtained.

There are two related though separate entities involved in the review and approval of human research: the Institutional Review Board Office and the Institutional Review Board.

The Institutional Review Board and the Institutional Review Board Office share the common mission of facilitating the ethical conduct of human research. There are three general areas of concern for human research subjects that are assessed in the research review and approval process.

- First, the respect for persons, including their autonomy to consent for research participation without coercion after being fully informed about the research process and procedures and their associated risks.

- Second are risks and benefits to the subjects that will be involved in the research. A determination must be made that they represent an acceptable balance for human research to be approved. Also considered under this area is the scientific design of the proposed research, as it is unethical to do research on humans which does not have a reasonable chance of answering the posed research question.

- Third is the concept of justice that involves issues of the populations targeted to the research and equal access to participate by all potential subjects. Discrimination regarding access on basis of sex, age, language spoken, ethnic or racial identity or economic status is not acceptable for research which has the potential to provide benefit to the subjects.

The Institutional Review Board convenes monthly to review all human research except for a few categories of minimal risk research which are approved administratively by the IRB Office. Protocols go through a pre-review process in which two board members identify items that need the Principal Investigator's attention prior to full board review. These reviewers are the Investigator's advocates and present the protocol at the full board meeting. The Investigator should work with the reviewers in addressing any concerns identified prior to the protocol going to the full board. Most protocols are conditionally approved with some further actions by the Investigator required for final approval.

The IRB Office provides administrative support and consultation to the IRB, but does not actively participate in IRB decisions regarding the approval of human research. The Office also serves as a liaison between investigators and the Board, providing guidance to investigators on protocol preparation and meeting requirements for final approval as identified by the Board.

The IRB Office has the institutional responsibility of monitoring the use of human subjects in research and documentation of the processes used to ensure the ethical use of human subjects. These processes have to meet extensive federal regulations and policies that are in place to protect the human research subjects' rights and ensure the ethical conduct of human research. As many of these apply to how the individual Investigator conducts the project, the IRB staff's responsibility extends to assisting each individual Investigator in meeting the regulations which apply to their research.

The IRB Office is the first point of contact in the human research review process. They will answer questions and provide assistance through the appropriate review path for the particular research protocol. The Office publishes an *Investigator's Handbook* that should be reviewed and read prior to starting the research review process. The Handbook describes many aspects of the approval requirements for various research activities and federal and Health Science Center policy that apply to ongoing research projects. A copy is available in the IRB Office. In addition to the *Investigator's*

Handbook, the Office will also provide a copy of the Health Science Center's Multiple Project Assurance. The Assurance is, in essence, a contract between the Health Science Center and the National Institutes of Health defining how human research will be reviewed and conducted. It outlines the responsibilities of the institution and the Investigator relating to human research that must be met to maintain the IRB's ability to review federally funded human research. The *Handbook* and the *Assurance* as well as links to federal guidelines and policies regarding human research are available at the IRB web site which can be accessed at http://research.uthscsa.edu/irb/.

9.2 Animal Subjects

The Health Science Center complies with the Animal Welfare Act (AWA), the Public Health Service Policy on Humane Care and Use of Laboratory Animals, the Guide for the Care and Use of Laboratory Animals, and the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training. The Health Science Center has an Animal Welfare Assurance on file with the NIH Office of Protection from Research Risks; the assurance number is A3345-01. The Health Science Center has been accredited by the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) since 1974.

All animals used for teaching, training, testing, research, and any related activity by faculty, staff and students in Health Science Center facilities must be used and cared for in accordance with all applicable provisions of the Animal Welfare Act, other federal statutes and regulations, accreditation guidelines, and institutional policies relating to the humane care and use of laboratory animals.

To accomplish this, the Health Science Center has established an Institutional Animal Care and Use Committee (IACUC) which oversees the animal care and use programs of the institution. The Department of Laboratory Animal Resources (DLAR) assumes responsibility for ensuring the best possible preventive, diagnostic and clinical care for animal subjects and for providing appropriate research support.

To ensure that the above goals are met, the Health Science Center requires that all research, teaching or testing programs that use laboratory animals be prospectively reviewed by the IACUC. Faculty members who intend to use either live or dead vertebrate animals for such purposes must submit an animal use protocol to the IACUC. No animals may be purchased or used without an approved animal protocol. Only the DLAR can purchase animals. The DLAR can be reached at x7-6166 or by accessing its web site at http://research.uthscsa.edu/lar/ .

9.3 Recombinant DNA Research and Biohazards

In compliance with NIH Guidelines and Health Science Center policies, an Institutional Biosafety Committee (IBC), registered with the National Institutes of Health, has been established. The Committee is charged with reviewing the use of research projects or clinical applications which involve recombinant DNA and/or replicating agents which are known or suspected pathogens. The IBC assesses risks involved and the measures proposed for the pathogen's containment. The IBC will review plans for areas designated to be constructed or remodeled for biohazardous work; and establish criteria and monitor adherence to these criteria for the use of biohazardous agents and facilities designed for use with such agents.

The Principal Investigator is required to apply for approval in the areas of Recombinant DNA, In Vitro Biohazard Research or Clinical laboratory use and In Vivo Biohazard use. Application forms used by the IBC in approval/disapproval are available in the Institutional Safety Office.

The Biohazard Safety Handbook provides information to assist the Principal Investigator in completion of the application to use Recombinant DNA and other biohazards as well a the procedures for safe handling of biohazardous material.

9.4 Radiation Safety

Radioactive isotopes and radiation producing machines at the Health Science Center are employed in teaching, diagnostic and therapeutic patient care, and research. The University holds a broad scope radioactive material license, x-ray and laser registration. The Health Science Center complies with the Texas Health and Human Services, Food and Drug Administration, Environmental Protection Agency, and Texas Commission on Environmental Quality regulation as well as local University policies and any licensing conditions. The license and registrations cover the University Health System as well as the Health Science Center.

In accordance with the license, the Radiation Safety Committee (RSC) has been established to make policy and review all use of radioactive material and protocols involving radiation. A Radiation Safety Handbook is provided for all persons working with radiation. The Handbook outlines the radiation safety requirements to meet training requirements, receive authorization, procure, use and dispose of radioactive material as well as requirements for radiation producing machines and human use of radiation. The Radiation Safety Committee meets bimonthly to review applications or

protocols from principal investigators for use of radiation in the laboratory, clinical or medical research setting. Review of protocols may run parallel with IRB review.

Application forms are available from Radiation Safety; the Radiation Worksheet required for human use protocols available from the IRB.

Each investigator using radiation at the Health Science Center is making a commitment to comply with University policy, state and federal regulations. The Radiation Safety Office will review all applications and protocols prior to submission to the RSC.

VA Medical Center use of radioactive material or protocols involving radiation requires authorization from the VA Radiation Safety Committee. Contact the VA Radiation Safety Office at x 94-4035 for information regarding the radiation use at the VA.

The Radioactive Drug Research Committee (RDRC) registered with the Food and Drug Administration is provided to review human use protocols using a radioactive drug in lieu of the investigator obtaining an IND from FDA. The RDRC serves the Health Science Center, the VA Medical Center and the University Health System. Contact the Radiation Safety Office to determine if a human use radioactive drug protocol must be reviewed by the RDRC as well as the RSC.

The Radiation Safety Office may be reached at x7-2955.

9.5 Chemical Carcinogens and Toxic Chemicals

A chemical safety program has been established at the Health Science Center to insure compliance with the Texas State Hazardous Communication Act and with good laboratory practices. The Chemical Safety Committee (CSC) will review the use of very toxic chemicals and in vivo use of a chemical carcinogen used to make a tumor. Additional areas of review may be added by the CSC. Principal Investigators are responsible for training their laboratory personnel in safe use and handling of the specific chemicals.

A Chemical Safety Handbook providing procedures for the safe handling and disposal of chemicals is distributed to every laboratory using chemicals.

Applications for approval by the CSC may be obtained from Institutional Safety. Contact Institutional Safety at x7-2955

9.6 Financial Conflict of Interest

The Health Science Center has developed policies and procedures for *Promoting Objectivity in Research by Managing, Reducing, or Eliminating Conflicts of Interest*. This policy was developed as a result of Public Health Service and National Science Foundation regulations promoting objectivity in research and in conjunction with certain Texas laws regarding standards of conduct and the Code of Ethics of The University of Texas System.

The full Financial Conflict of Interest policy is available at http://uthscsa.edu/hop2000/10.1.6.pdf.

9.7 Misconduct in Science

Consistent with the requirements of several federal agencies, the Health Science Center has adopted a policy with respect to allegations of misconduct or fraud in the conduct of sponsored programs. The policy, entitled "Research Fraud/Misconduct Policy" can be found in the *Handbook of Operating Procedures*.

9.8 Research Activities Performed by Outside Organizations

The Health Science Center recognizes that from time to time it may be appropriate for an outside organization to perform research activities at the Health Science Center. The Health Science Center will consider requests for such activities based on the following guidelines:

a) University faculty research must have priority over all private-sector research with respect to all resources including facilities, equipment, services, and personnel.
b) The services that are to be provided to the outside company should be for stated periods of time rather than permanent.
c) The research being conducted in the University facilities must be within the research mission of at least one of the Health Science Center's departments.
d) The Health Science Center will receive reimbursement for all costs associated with each individual project. Such reimbursement shall include incremental costs incurred by the Health Science Center as a result of the use plus the appropriate indirect cost for sponsored projects.
e) The Health Science Center will not make its facilities available for services that are available from the private sector in the San Antonio area. This guideline would apply to the basic purpose for which facilities are used and not to all ancillary services.

f) All companies must have a sponsoring department that is willing to certify to at least the following:
   i) The department has the space available for the outside company to perform the project.
   ii) The project will not take away from any of the department's functions or activities.
   iii) The department will be responsible for all administrative details relating to the proposed company's use of the facilities, such as obtaining temporary parking permits through University Police, arranging for keys, etc.
   iv) If University resources for which the Health Science Center has an obligation to a third party are to be used, the sponsoring department will appoint a faculty member who will be responsible for the conduct of the outside company relating to those resources.
g) All such arrangements should be subject to a business agreement to be negotiated by the Office of the Vice President for Administration and Business Affairs upon the recommendation of the sponsoring department and the appropriate dean, with final approval by the President.

9.9 F&A (Indirect) Cost Recovery 

It is the policy of the Health Science Center to require F&A (indirect) cost recovery on all non-Federal sponsored programs. This rate will be either the established policy of the donor, if known, or a minimum of 26% of total direct costs of the project.

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APPENDIX A

ACRONYMS USED IN SPONSORED PROJECTS ADMINISTRATION

AAALAC	**American Association of Animal Laboratory Accreditation Council**
ACO	**Administrative Contracting Officer**
ACS	**American Cancer Society**
ACTA	**Accelerated Clinical Trail Agreement**
AFOSR	**Air Force Office of Scientific Research**
AHA	**American Heart Association**
ARO	**Army Research Office**
ARPA	**Advanced Research Projects Agency**
AUTM	**Association of University Technology Managers**
BAA	**Broad Agency Announcement**
CAS	**Cost Accounting Standards**
CASB	**Cost Accounting Standards Board**
CBD	**Commerce Business Daily**
CDA	**Confidential Disclosure Agreement**
CFDA	**Catalog of Federal Domestic Assistance**
CFR	**Code of Federal Regulations**
CO	**Contracting Officer**
COGR	**Council on Governmental Relations**
COI	**Conflict of Interest**
COP	**Certificate/Certification of Proposal**
CRADA	**Cooperative Research and Development Agreement**
CTA	**Clinical Trial Agreement**
CTSA	**Clinical and Translational Science Awards**
DA	**Departmental Administration**
DC	**Direct Costs**
DCA	**Division of Cost Allocation (HHS)**
DCAA	**Defense Contract Audit Agency**
DCE	**Direct Cost Equivalent**
DEAR	**Department of Energy Acquisition Regulations**
DFAR	**Defense Federal Acquisition Regulations**
DHEW	**Department of Health, Education and Welfare (replaced by DHHS)**
DHHS	**Department of Health and Human Services**
DOD	**Department of Defense**
DOE	**Department of Energy**
DOEd	**Department of Education**
EDGAR	**Education Department General Administration Regulations**

EDI	**Electronic Data Interchange**
EFT	**Electronic Funds Transfer**
EPA	**Environmental Protection Agency**
ERA	**Electronic Research Administration**
F & A	**Facilities and Administration Costs (formerly Indirect Costs)**
FAR	**Federal Acquisition Regulations**
FDP	**Federal Demonstration Partnership (previously Federal Demonstration Project, Florida Demonstration Project)**
FEDIX	**On-line federal database serving most federal agencies**
FIE	**Federal Information Exchange**
FIPSE	**Fund for the Improvement of Postsecondary Education**
FOIA	**Freedom of Information Act**
FSR	**Financial Status Report**
GA	**General Administration**
GSA	**General Services Administration**
IACUC	**Institutional Animal Care and Use Program**
IDC	**Indirect Costs (now called Facilities and Administration Costs)**
IG	**Inspector General**
IRB	**Institutional Review Board (Human Subjects)**
IR&D	**Independent Research and Development**
LAR	**Laboratory Animal Resources**
MOU	**Memorandum of Understanding**
MTA	**Material Transfer Agreement**
MTDC	**Modified Total Direct Costs**
NAM	**New Account Memorandum**
NASA	**National Aeronautics and Space Administration**
NCURA	**National Council of University Research Administrators**
NDA	**Non-Disclosure Agreement**
NEA	**National Endowment for the Arts**
NEH	**National Endowment for the Humanities**
NFAH	**National Foundation on the Arts and Humanities**
NIH	**National Institutes of Health**
NRSA	**National Research Service Award**
NSF	**National Science Foundation**
OMB	**Office of Management and Budget**
ONR	**Office of Naval Research**
OPRR	**Office of Protection from Research Risks**
OSHA	**Occupational Safety and Health Administration**
OSI	**Office of Scientific Integrity**
OSP	**Office of Sponsored Programs**
OSTP	**Office of Science and Technology Policy**
PA	**Program Announcement**
PETA	**People for the Ethical Treatment of Animals**
PHS	**Public Health Service**

PI	**Principal Investigator**
RDNA	**Recombinant DNA**
RFA	**Request for Applications**
RFP	**Request for Proposal**
RFQ	**Request for Quotation**
SBIR	**Small Business Innovation Research**
SPA	**Sponsored Program Administration**
SPIN	**Sponsored Programs Information Network**
SRA	**Society of Research Administrators**
STTR	**Small Business Technology Transfer**
TDC	**Total Direct Costs**
UBIT	**Unrelated Business Income Tax**
UG	**OMB Uniform Guidance**
USC	**United States Code**
USDA	**United States Department of Agriculture**

APPENDIX B

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APPENDIX C

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APPENDIX D

SAMPLE PROPOSAL COVER PAGE

This is a sample format for a proposal cover page.

PROPOSAL

To the

<SPONSOR>

Submitted by the

University of Texas Health Science Center at San Antonio

Project Title:

Period Performance:

Date Submitted:

Principal Investigator(s): <name, title, unit>

Endorsements:

_____	_____	_____	_____
Principal Investigator <Name, Telephone No.>	Date	Authorizing Official Chris G. Green, CPA Senior Director, Sponsored Programs Office of Sponsored Programs	Date

Inquiries regarding contract or grant negotiations and business correspondence should be directed to the Office of Sponsored Programs, University of Texas Health Science Center at San Antonio, 7703 Floyd Curl Drive, San Antonio, TX 78229-3900, tel. 210.567.2340, fax 210.567.8107

APPENDIX E

Proposal Budgeting Information Table

This table provides helpful hints, rules, and information for preparing proposal budgets.

DIRECT COSTS: Direct Costs are costs that can be specifically identified with a particular sponsored project. Direct Costs may include salaries, fringe benefits, equipment, travel, subawards, tuition (on training grants), and operations expenses such as materials and supplies, consultants, photocopying/printing, and long distance telephone toll charges.

NOTE: Due to provisions in the OMB Uniform Guidance, if requesting direct charges for salaries of administrative and clerical staff, office supplies, postage, local telephone costs and memberships, a justification for direct charging should be included in the proposal budget. On NIH modular grants programs, a special internal budget form has been prepared to show these costs.

SALARIES AND WAGES

- List the amount of time (percent of effort) to be spent by each Health Science Center employee who will work on the project and the rate of pay (institutional base salary), when requested.
- Compensation on sponsored projects must not exceed the authorized base rate of pay at the Health Science Center or sponsor-imposed salary caps.
- New job classifications and compensation for staff must conform to Health Science Center classifications.
- Time should be shown in percent of full-time effort.
- Effective 01/2018, the NIH salary cap is $189,600. Fringe benefits should be calculated on the Health Science Center base rate of pay, not the capped salary amount.
- Compensation (wages and fringe benefits) for graduate students paid from NIH funds should normally not exceed $36,996 per year.
- Use an annual escalation factor of 3% for NIH; 3-4% for other sponsors, unless otherwise restricted.
- Budgeting for secretarial/administrative support on projects is appropriate only when effort can be specifically identified with the project and such effort is significant (10% or more). Federal sponsors are now requiring additional justification of the need for these positions.
- Budget undergraduate student employees starting at $7.25/hour. Increases may be added based on experience and policies of the Office of Human Resources.

FRINGE BENEFITS (effective 9/1/10)

Faculty Staff	26% of salary 30% of salary	Covers FICA, health insurance, unemployment and worker's compensation, retirement, etc.
Postdoctoral Employees Full-time 20 hrs/wk or under	 30% of salary 10% of salary	 Same as faculty/staff Covers statutory benefits (FICA, etc.)
Graduate Students over 20 hrs/wk 20 hrs/wk or under	 15% of salary 10%	 Same as part-time faculty/staff Covers statutory benefits (FICA, etc.)
Undergraduate Students over 20 hrs/wk 20 hrs/wk or under	 15% of salary 10% of salary	 Same as part-time faculty/staff Covers statutory benefits (FICA, etc.)
Temporary Employees	10% of salary	Covers statutory benefits (FICA, etc.)

EQUIPMENT
Separately list any equipment purchase (defined as having a useful life of at least one year and an acquisition cost of $5,000 or more per unit). Equipment leases should be listed in operations costs. Equipment requests are strengthened by including the basis of the cost of proposed equipment, i.e., telephone quotes, vendor catalog prices or bids.

TRAVEL
Follow Health Science Center policies listed in the Handbook of Operating Procedures, *Section 6.2 - Travel Policies and Procedures* for travel expenses. Transportation equals the estimated round-trip airfare at lowest possible fares or $.56 per mile if driving is appropriate. Per diem costs (lodging, meals, and incidentals) should be estimated using the rates provided in the HSC Handbook of Operating Procedures, *Section 6.2.22 - Meals and Lodging Expenses* on Travel Vouchers. Proposed travel should include conference name (if applicable), location, purpose and cost. Foreign travel should be budgeted separately and may require additional prior written approval from sponsor.

MAINTENANCE AND OPERATIONS
Maintenance and Operations costs include but are not limited to:

Category	Cost Estimation Basis
Expendable materials and supplies	Best estimate: check catalogs and historical records
Publication charges	Use historical estimate; add more for color
Copy services	Best estimate: $.08/copy
Long distance telephone, fax, network charges	Best estimate
Postage/express mail	Best estimate: $0.50 for 1 oz. Letter
Office supplies	Best estimate: check catalogs and historical records
Equipment maintenance	Best estimate: check historical records or contact Purchasing
Consultants	Actual daily rate and expenses with proper documentation
Subawards	Authorized budget or written estimate/quotation on subawardee letterhead with authorized signature – refer to sponsor guidelines
Renovation	Contact Health Science Center Facilities Department for estimate
Lab animal costs	Contact Laboratory for Animal Resources for per diem and purchase rates

TUITION AND FEES
Current tuition and fee schedules can be found at HSC website under student services. Except in unusual circumstances, tuition/fees on research grants for Graduate Research Assistants should be charged at the in-state tuition rate.

F&A OR INDIRECT COSTS: F&A costs are costs that cannot be specifically identified with a sponsored project, but which benefit that project (e.g., purchasing utilities, payroll, facilities, and department administration).

F&A (INDIRECT COST) CALCULATION
When full F&A are allowable, apply the appropriate F&A rate to the modified total direct costs (MTDC) base. Items included in the MTDC base are:

♦salaries and wages	♦copy services	♦computer software	♦publication/page charges
♦fringe benefits	♦first $25,000 of subcontracts	♦materials and lab supplies	♦consultant services
♦travel	♦communications costs (telephone and mailing)	♦office supplies	♦any other costs not listed below

Items not in the MTDC base are: (exclude these from base calculation)

- Equipment
- Capital expenditures (construction and renovation)
- Charges for patient care (e.g., tests, bed costs)
- Tuition remission
- Rental costs of off-site facilities
- Scholarships and fellowships (not allowable on research projects)
- Subaward amounts in excess of $25,000

If the rate used or prescribed by the sponsor is less than the Health Science Center's negotiated rate, F&A may be calculated on total direct costs or some other basis instead of modified total direct costs. Contact OSP for assistance.

Indirect Cost Rates

These rates were negotiated with the Department of Health and Human Services; date of agreement is November 17, 2014. These rates are classified as predetermined.

Applicable to:	Location	Effective 11/17/14 until amended
Research	On-campus	52.5% MTDC
	Off-campus*	26.0% MTDC
Instruction	On-campus	45.0% MTDC
Other Sponsored Activities	On Campus	39.0% MTDC
Industry-Sponsored Research, Clinical Trials, SBIR/STTR Phase I	Any	26.0% TDC**

*Off-campus is defined as any facilities not owned by the Health Science Center and to which rent is directly allocated to the projects. Agreements should use only one F&A cost rate; if more than 50% is performed off-campus, the off-campus rate applies to the entire project.
**No modifiers are to be used in calculating this rate with the possible exception of bed-costs.

A rate of 26% TDC should be used on grants and agreements from all other private sponsor types such as nonprofit organizations and foundations, unless indirect costs are specifically restricted or prohibited by the sponsor.

APPENDIX F

Guidance for Calculation of Salaries of Personnel With VA Appointments

Investigators with VA appointments must disclose their joint appointment in the budget justification of their NIH proposals. The justification should disclose what portion of the effort committed will be from their Health Science Center effort and what portion, if any, will be from their VA effort.

In preparing proposals, specifically budget justifications, UTHSCSA faculty who hold VA salaried appointments should include the standard statement (below) to disclose to NIH the basis for the effort percentage and salary request.

Dr. _____ has an appointment with the University of Texas Health Science Center at San Antonio (UTHSCSA) and the Veterans Administration (VA). This arrangement is defined in a formal UTHSCSA-VA Joint Appointment Memorandum of Understanding (MOU). The institutional base salary used in this application represents only the salary from UTHSCSA. Dr. _____'s university committed effort on this proposal is ____ calendar months, or ___% of a ___% HSC appointment, of which salary has been requested. It is further clarified that Dr. _____ receives salaries from both the UTHSCSA and VA and that there is no dual compensation from these two sources for the same work nor is there an actual or apparent conflict of interest regarding such work.

For those cases in which a portion of the VA appointment will also be committed to the NIH project, the following statement should also be inserted in the budget justification:

Dr. _____'s VA effort commitment on this proposal is ___ calendar months, or ___% of his/her VA appointment for which no salary is being requested.

The full policy is available at:

http://research.uthscsa.edu/osp/forms/OSP_VA_MOU_Guidelines.doc

MOU FAQ's are available at:

http://research.uthscsa.edu/osp/forms/VA_MOU_FAQ.docx

APPENDIX G

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APPENDIX H

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APPENDIX I

Direct Cost Guidelines

The federal government is the largest sponsor of research and other scholarly activities at the Health Science Center. For that reason, the cost policies of the federal government, contained in OMB Uniform Guidance, provide guidance for all sponsored activities. The table below gives information regarding the allowability of some of the most common items of costs charged as direct. *In the case of an inconsistency between the provisions of a specific agreement and the provisions below, the provisions of the specific agreement should govern.* It is also recognized that the Health Science Center enters into agreements with private sponsors who have no specific rules regarding costing policies. If those agreements are not for research projects but are for other activities, certain exceptions to the following guidelines may be made.

Cost	Normal Treatment
Salaries, Wages and Benefits • **Faculty** • **Postdoctoral Fellows** • **Graduate Students** • **Undergraduate Students** • **Technical Personnel** • **Administrative & Clerical**	**Costs of personnel are allowable on research agreements to the extent supported by actual effort performed on the project and approved in the award budget. Effort Certifications will be used to document the actual effort performed. An individual's base salary must be used to compute the cost charged to a sponsored agreement; extra-compensation or supplemental pay for work on sponsored programs is unallowable except in extraordinary circumstances and with specific agency permission.** **Administrative and Clerical costs are generally recovered through indirect costs; therefore, they are usually unallowable as direct costs on federal agreements.** **For all federal awards, Administrative and clerical salaries must be explicitly included in the budget or have the prior written approval of the awarding agency.**
Business Meals and Meeting Costs	**Only when specifically permitted by the sponsored agreement.**
Donations and Contributions	**Unallowable**
Entertainment Costs	**Unallowable unless specifically approved.**
Equipment	**Scientific: Allowable when the equipment is necessary and will be used primarily, or exclusively, for the project(s) to which the costs will be charged.** **General Purpose (e.g., desks, file cabinets, fax machines, computers): Unallowable unless specifically approved in the sponsored agreement or subsequently approved by sponsor. In the case of computer, if computer is essential to the performance of the work.**
Local Telephone (including	**Generally unallowable as a direct cost. However, there are**

Cost	Normal Treatment
monthly instrument charges)	**certain circumstances where these charges may be directly charged to a research project such as instances where patients call in to a specific telephone line.**
Long Distance Telephone	**Allowable when specifically identified with an individual project.**
Materials (supplies, purchased materials, etc.)	**Project Supplies: Items such as chemicals, laboratory supplies and even pens, pencils, folders, notebooks and the like that can be identified as being "exclusively for the support" of a sponsored agreement are allowable.** **Office Supplies: Items commonly found in any office such as wall clocks, calendars, waste cans, letterhead, staplers, etc. that would likely be used for other purposes are unallowable except in specific circumstances.**
Memberships (scientific or professional societies)	**Unallowable unless specifically approved by the sponsor.**
Postage	**Routine Postage Costs: Unallowable except where a project requires specifically identifiable large mailings or the like.** **Special Mailing or Delivery Costs: Allowable when necessary for the success or completion of project (example: overnight delivery charges for shipment of research materials to collaborators or from suppliers)**
Pre-agreement Costs	**Unallowable unless approved under the provisions of the specific funding agency.**
Professional Services	**Consultant fees are an allowable charge to sponsored agreements. Sponsor guidelines should be checked. "Honorariums" are typically not allowed; rather, payments to consultants are for services received.**
Publications (books, subscriptions)	**Unallowable unless approved by the funding agency or essential to the daily conduct of the project and not readily available from other sources (such as the library).**
Scholarships and Student Aid	**Unallowable to research projects**
Travel Costs	**Allowable if specifically benefiting project.** **Foreign travel using federal funds: U.S. flag carrier rules apply; may require specific agency approval; consult sponsor regs.**
Visa Costs	**Short-term, travel visa costs (as opposed to longer-term immigration visas) are generally allowable expenses that may be proposed as a direct cost. Since short-term visas are issued for a specific period, they can be identified as directly connected to participation on a Federal award. For these costs to be directly charged to a Federal award, they must:** • **Be critical and necessary for the conduct of the project;** • **Be allowable under the applicable cost principles;** • **Be consistent with the University's cost accounting**

Cost	Normal Treatment
	practices and policies; and • **Meet the definition of "direct cost" as described in the applicable cost principles.** **[Reference: 2 CFR Part 200.463(d)]**

APPENDIX J

Access to and Retention of Research Data

Background

Research data is created at the Health Science Center by faculty, staff, and students in the course of their scholarly activities and often while conducted sponsored programs funded by external sponsors. By tradition and for practical reasons, the creators of the data retain control to access and use of that data even though the Health Science Center, through contractual or other agreements with external sponsors, may be required to hold title to or own the data. Because of those obligations, the Health Science Center recognizes that it has responsibilities with respect to access and retention of data, particularly data generated under sponsored agreements.

Policy

Research data created while individuals are pursuing research studies as faculty, staff, or students of the Health Science Center and data created by visiting scientists or the like utilizing the facilities of the Health Science Center are to be retained by the Health Science Center for a period of three (3) years after submission of the final report on the research project for which the data were collected, unless a longer period is specified by the sponsor.

The original research data shall be in the custody of the senior investigator on behalf of the Health Science Center, but must be returned to the Health Science Center upon request of the President or designee. Additionally, such data must be available to representatives of external sponsors of the research or designed government officials, when such access is appropriate. Such data must not be destroyed or altered during the time period referenced above unless explicit written approval for such disposition is received from the President or designee.

Information Related to Policy Statement

Definition of Data

As used in this policy data means recorded information, regardless of the form or the media that records it. The term includes computer software, computer programs, computer databases (and documentation thereof), and data of a scientific or technical nature. For the purposes of this policy the term does not include information incidental to award administration, such as financial, administrative, cost or pricing, or management information. In practice, scientific data includes, but is not limited to, materials contained in laboratory notebooks or other media such as computer disks and

machine printouts. Data also includes both intangible data (statistics, findings, conclusions, etc.) and tangible data (notebooks, printouts, etc.)

Investigator Responsibilities at the Health Science Center

It is important that investigators have the ability to document the results of research, both for the sake of assisting the Health Science Center in meeting its scholarly and legal requirements as well as for the more traditional reasons of establishing priority for patentable items, publishing manuscripts, and the like. Senior members of research teams have obligations to discuss the responsibilities of data management and retention and other members of a research team. As a matter of practice, original data should be left with the senior investigator when a student leaves the institution, but copies of that data, where feasible to do so, should be provided to the student.

Investigator Responsibilities After Leaving the Health Science Center

When an investigator leaves the Health Science Center, he or she must recognize that the Health Science Center must have access to the data. It is neither feasible nor desirable for the original research records to remain at the Health Science Center. Departing investigators must understand that they have an obligation to hold these data in trust for the Health Science Center and that such data must be returned to the Health Science Center, if requested, during the three (3) year period after submission of the final report on the research project for which the data were collected, unless a longer retention period was specified by the sponsor.

APPENDIX K

Sample Sponsored Research Agreement

THIS Agreement is made this _____ day of _____, 20__ ("Effective Date"), between The University of Texas Health Science Center at San Antonio, with an address at 7703 Floyd Curl Drive, MSC 7828, San Antonio, Texas 78229-3900 ("Institution"), an institution of The University of Texas System ("System"), and _____ ("Sponsor"), with an address at _____. Institution and Sponsor agree as follows:

1. PROTOCOL

1.1 Institution agrees to use reasonable efforts to conduct a research project, as an independent contractor, in accordance with Institutional policy, applicable laws and regulations and the Project, "[INSERT TITLE OF PROJECT]" as described in Exhibit A attached hereto and incorporated herein ("Study"). The Study will be supervised by _____, M.D. [or Ph.D., REVISE ACCORDINGLY], ("Principal Investigator"), an employee at Institution but not a party to this agreement, with assistance from associates and colleagues as required.

1.2 Sponsor agrees to engage the services of Institution to conduct the Study and further agrees to provide at no cost to Institution the [samples, drugs, materials] for the conduct of the Study.

2. AWARD

2.1 In consideration for performance of the Study by Institution, Sponsor shall pay Institution $_____ for Study expenses and other related costs. This amount, shown by approximate category of expenses in Exhibit B attached hereto for information only, is payable in _____ installments in the amount of $_____ each. The first payment is payable within 30 days of the Effective Date and the final payment will be due upon completion of the Study.

3. TERM AND TERMINATION

3.1 This Agreement shall continue in force until the earlier of (i) completion of the Study as mutually agreed upon by the parties; or (ii) _____ months from the date set forth above; provided, however, that either party may terminate this Agreement by giving 30 days advance notice to the other.

3.2 Upon early termination of this Agreement, Sponsor shall be liable for all reasonable costs incurred or obligated by Institution at the time of such termination, subject to the maximum amount specified in Article 2. Sponsor shall pay Institution for such costs within 30 days of receipt of an invoice for same.

3.3 Upon termination of this Agreement, Institution shall return Sponsor's materials and equipment to Sponsor.

4. INDEMNIFICATION

4.1 Institution shall, to the extent authorized under the Constitution and laws of the State of Texas, indemnify and hold Sponsor harmless from liability resulting from the negligent acts or omissions of Institution, its agents or employees pertaining to the activities to be carried out pursuant to the obligations of this Agreement; provided, however, that Institution shall not hold Sponsor harmless from claims arising out of the negligence or willful malfeasance of Sponsor, its officers, agents, or employees, or any person or entity not subject to Institution's supervision or control.

4.2 Sponsor shall indemnify and hold harmless System, Institution, their Regents, officers, agents and employees from any liability or loss resulting from judgments or claims against them arising out of the activities to be carried out pursuant to the obligation of this Agreement, including but not limited to the use by Sponsor of the results of the Study; provided, however, that the following is excluded from Sponsor's obligation to indemnify and hold harmless:

a. the negligent failure of Institution to comply with any applicable governmental requirements or to adhere to the terms of the Protocol; or

b. the negligence or willful malfeasance by a Regent, officer, agent, or employee of Institution or System.

4.3 The parties acknowledge that Institution and System are agencies of the State of Texas and under the Constitution and laws of the State of Texas possess certain rights and privileges and only have such authority as is granted to them under the Constitution and laws of the State of Texas. Nothing in this Agreement is intended to be, nor will it be construed to be, a waiver of the sovereign immunity of the State of Texas or a prospective waiver or restriction of any of the rights, remedies, claims, and privileges of the State of Texas.

5. INVENTIONS

5.1 Ideas, know-how, data (including study results), and other intellectual property generated under this Agreement shall be the sole and exclusive property of the employer of the author or inventing party and inventorship shall be determined in accordance with U.S. Patent laws.

6. PUBLICATION AND CONFIDENTIALITY

6.1 Institution reserves the right to publish the results of the Study, with due regard to the protection of Sponsor’s confidential information. Institution will submit the manuscript of the proposed publication to Sponsor at least thirty (30) days prior to publication, and Sponsor shall have the right to review and comment upon the publication in order to protect Sponsor’s confidential information. The Institution shall consider Sponsor’s suggestions and comments to the manuscript to be published. Upon Sponsor’s written request, publication will be delayed up to sixty (60) additional days to enable Sponsor to secure adequate intellectual property protection on Sponsor’s intellectual property that would be affected by said publication.

6.2 Neither party shall reference the other in a press release or in any other written or oral statement in connection with work performed under this Agreement if it is intended for use in the public media or for commercial purposes, except as required by the Texas Public Information Act or other law or regulation. Institution shall have the right to acknowledge Sponsor's support of the study in scientific or academic publications and other scientific or academic communications without Sponsor's prior approval. In any such statements, the parties shall describe the scope and nature of their participation accurately and appropriately.

6.3 Each party shall hold in confidence for three (3) years after the termination of this Agreement any confidential information directly related to the Study, identified in writing as confidential, and obtained from the other party during the term of this Study. Nothing herein, however, shall prevent Institution or any other component of System from using any information generated hereunder for ordinary research and educational purposes. The recipient party's obligation shall not apply to information that:

i. is not disclosed in writing and marked as Confidential or reduced to writing and marked with an appropriate confidentiality legend within thirty (30) days after disclosure;
ii. is already in the recipient party's possession at the time of disclosure;
iii. is or later becomes part of the public domain through no fault of the recipient party;
iv. is received from a third party having no obligations of confidentiality to the disclosing party;
v. is independently developed by the recipient party; or
vi. is required by law or regulation to be disclosed.

In the event that information is required to be disclosed pursuant to subsection (vi), the party required to make disclosure shall notify the other to allow that party to assert whatever exclusions or exemptions may be available to it under such law or regulation.

7. GENERAL

7.1 This Agreement, including the attached Exhibits A and B, constitutes the entire and only Agreement between the parties relating to the Study, and all prior negotiations, representations, agreements, and understandings are superseded hereby. No agreements altering or supplementing the terms hereof, including the exhibits attached hereto may be made except by a written document signed by the duly authorized representatives of the parties.

7.2 Any conflicts between the Project and this Agreement are controlled by this Agreement.

7.3 This Agreement shall be construed and enforced in accordance with the laws of the State of Texas.

7.4 This Agreement anticipates educational training and may involve health science postgraduates and other students of the Institution.

7.5 Any notice required by this Agreement must be given by prepaid, first class, certified mail, return receipt requested, addressed to:

INSTITUTION
The University of Texas Health Science Center at San Antonio
Mail Code 7828
7703 Floyd Curl Drive
San Antonio, TX 78229-3900
ATTENTION: Senior Director
FAX: 210.567.8107
PHONE: 210.567.2340

or in the case of SPONSOR to:

_____
_____
_____
ATTENTION: _____
FAX: _____
PHONE: _____

or other addresses as may be given from time to time under the terms of this notice provision.

7.6 Signatures to this Agreement transmitted by fax, by electronic mail in "portable document format" (".pdf"), or by any other electronic means intended to preserve the original graphic and pictorial appearance of the Agreement, shall have the same effect as physical delivery of the paper document bearing the original signature.

IN WITNESS WHEREOF, Institution and Sponsor hereby enter into this Agreement as of the Effective Date, and execute 2 original counterparts.

SPONSOR

By: _____
Name: _____
Title: _____

Date:
_____

The University of Texas Health Science Center at San Antonio

By:_____
Chris G. Green, CPA
Senior Director
Office of Sponsored Programs

Date: _____

I have read this Agreement and understand my obligation hereunder:

By: _____
Principal Investigator

Date: _____

Make Payment to:
The University of Texas Health Science Center at San Antonio
Attn: [INSERT PI NAME & DIVISION/DEPARTMENT]
7703 Floyd Curl Drive
San Antonio, TX 78229-3900
Tax I.D. 74-1586031

APPENDIX L

SAMPLE CLINICAL STUDY AGREEMENT

("Clinical Trial Title")

THIS Agreement is made this ___ day of _____, 200_ , between The University of Texas Health Science Center at San Antonio ("Institution"), an institution of The University of Texas System ("System") with an address at 7703 Floyd Curl Drive, MSC 7828, San Antonio, TX 78229-3900, and (Company Name), (Company's address) ("Sponsor"), to conduct a clinical study and evaluation ("Study"). Institution and Sponsor agree as follows:

1. CONDUCT OF THE STUDY

1.1 Institution agrees to use reasonable efforts to conduct the Study as an independent contractor, in accordance with Institutional policy and ethical standards, applicable laws and regulations, and the Protocol Number (#), "(Study title)", as described in Exhibit A ("Protocol"). The Study will be supervised at Institution by (name of Principal Investigator) ("Principal Investigator"), an employee of Institution, with assistance from associates and colleagues as required.

1.2 Sponsor agrees to engage the services of Institution to conduct the Study and further agrees to provide at no cost to Institution the (drug, materials, or equipment) for the conduct of the Study.

2. AWARD

2.1 In consideration for performance of the Study by Institution, Sponsor shall pay Institution (spell out amount) Dollars ($) for Study expenses for the clinical study, involving approximately (number) patients, and other related costs. This amount, shown by approximate category of expense in Exhibit B, is payable in (number) installments of (spell out amount) Dollars ($) each by Sponsor to Institution. The first installment is payable within thirty (30) days of the date set forth above, and subsequent installments are payable on a quarterly basis upon receipt by Sponsor of interim case reports for: (a) one- third (1/3) of the final patient enrollment; (b) two-thirds (2/3) of the final patient enrollment; and (c) the remaining patient enrollment and Study close out, or as otherwise agreed upon by both parties in a written amendment to this Agreement.

3. TERM

3.1 This Agreement shall continue in force until the earlier of either (a) completion of the Study as mutually agreed upon by the parties , or (b) (number) month(s) from the date set forth above; provided, however that either party may terminate the Agreement by giving thirty (30) days advance written notice to the other.

3.2 Upon early termination of this Agreement, Sponsor shall be liable for all reasonable costs incurred or obligated by Institution at the time of such termination, subject to the maximum amount specified in Article 2. Sponsor shall pay Institution for such costs within thirty (30) days of receipt of an invoice for same.

3.3 Upon termination of this Agreement, Institution shall return Sponsor's materials and equipment to Sponsor.

4. INDEMNIFICATION AND LIABILITY

4.1 Institution shall, to the extent authorized under the Constitution and laws of the State of Texas, indemnify and hold Sponsor harmless from liability resulting from the negligent acts or omissions of Institution, its agents or employees pertaining to the activities to be carried out pursuant to the obligations of this Agreement; provided, however, that Institution shall not hold Sponsor harmless from claims arising out of the negligence or willful malfeasance of Sponsor, its officers, agents, or employees, or any person or entity not subject to Institution's supervision or control.

4.2 Sponsor shall indemnify and hold harmless System, Institution, their Regents, officers, agents and employees from any liability or loss resulting from judgments or claims against them arising out of the activities to be carried out pursuant to the obligation of this Agreement, including but not limited to the use by Sponsor of the results of the Study; provided however, that the following shall be excluded from Sponsor's obligation to indemnify and hold harmless:

a. the negligent failure of Institution to comply with any applicable governmental requirements or to adhere to the terms of the Protocol; or

b. the negligence or willful malfeasance by a Regent, officer, agent, or employee of Institution or System.

4.3 If a Study participant is injured from the Study drug or a procedure that is required solely for Study purposes, Sponsor will be responsible to cover the cost of treating that injury. Full financial responsibility for payment of such expenses resulting from an injury or illness suffered in the course of the Study will rest with the Sponsor, except to the extent that such expenses are attributable to the negligence or willful misconduct of the Institution.

5. PUBLICATION, CONFIDENTIALITY, AND INTELLECTUAL PROPERTY

5.1 The parties reserve the right to publish or otherwise make public the data resulting from the Study. Any such publication shall be made in accordance with Institution policies and procedures concerning findings from sponsored research. The party wishing to publish or make public shall submit any such manuscript or release to the other party for comment prior to publication or release.

5.2 Except as otherwise required by law or regulation, neither party shall release or distribute any materials or information containing the name of the other party or any of its employees without prior written approval by an authorized representative of the non- releasing party, but such approval shall not be unreasonably withheld.

5.3 Each party shall hold in confidence for three (3) years after the termination of this Agreement any confidential information identified as confidential and obtained from the other party during the course of this Study. Nothing herein, however, shall prevent Institution or any other component of System from using any information generated hereunder for ordinary research and educational purposes of a university. The recipient party's obligation shall not apply to information that:

vii. is not disclosed in writing or reduced to writing and marked with an appropriate confidentiality legend within thirty (30) days after disclosure;
viii. is already in the recipient party's possession at the time of disclosure;
ix. is or later becomes part of the public domain through no fault of the recipient party;
x. is received from a third party having no obligations of confidentiality to the disclosing party;
xi. is independently developed by the recipient party;
xii. is ethically required to be disclosed to participants because of any unforeseen risk identified by either party during or after completion of the Study; or
xiii. is required by law or regulation to be disclosed.

In the event that information is required to be disclosed pursuant to subsection (vii), the party required to make disclosure shall notify the other to allow that party to assert whatever exclusions or exemptions may be available to it under such law or regulation.

5.4 Title to all inventions and discoveries made by Institution resulting from the research performed hereunder shall reside in Institution; title to all inventions and discoveries made by Sponsor resulting from the research performed hereunder shall reside in Sponsor; title to all inventions and discoveries made jointly by Institution and Sponsor resulting from the research performed hereunder shall reside jointly in Institution and Sponsor. Inventorship shall be determined in accordance with U.S. Patent law.

5.5 After consultation with Sponsor regarding the advisability of filing patent applications, Institution shall file appropriate United States and foreign patent applications for wholly or jointly owned Institution inventions. Institution will provide Sponsor, on a confidential basis, a copy of any such application filed and any documents received or filed during prosecution thereof and will provide Sponsor the opportunity to comment thereon. On any application on which an employee of Sponsor is named as a co-inventor, Sponsor will cooperate in obtaining execution of any necessary documents by its employees.

5.6 Institution agrees to grant to Sponsor an option to negotiate an exclusive, worldwide, royalty-bearing license to make, use or sell under any invention or discovery owned wholly or partly by Institution and made or conceived and reduced to practice during the term of this Agreement or within six (6) months thereafter and directly resulting from the performance of the research hereunder, with right to sublicense with accounting to University. Sponsor shall have three (3) months from disclosure of any invention or discovery to notify Institution of its desire to enter into such a license agreement, and a license agreement shall be negotiated in good faith within a period not to exceed six (6) months from Sponsor's notification to Institution of its desire to enter into a license agreement, or such period of time as to which the parties shall mutually agree.

5.7 If Sponsor and Institution fail to enter into an agreement during that period of time, Sponsor shall have a right of first refusal with respect to any terms generally more favorable offered by Institution to a third party for a period of one (1) year thereafter.

5.8 In the event Sponsor elects to exercise its option to negotiate a license in accordance with the procedures detailed above, it shall be obligated to pay all expenses, including attorney's fees, incurred in searching prior art, obtaining search opinions, preparing applications, filing, prosecuting, enforcing or maintaining a patent or patent application with respect to the licensed invention in any country in which the patent or application is filed.

6. NOTICES CONCERNING PARTICIPANT SAFETY

6.1 The parties shall promptly provide notice to each other of any information discovered by either respective party through any means including but not limited to monitoring, audits, or analysis of Study results, if such information could:

i. affect the safety of current or former Study participants;
ii. affect the willingness of Study participants to continue participation;
iii. influence the conduct of the Study; or
iv. alter the IRB approval to continue the Study.

Institution shall promptly notify its IRB of any such events. When participant safety or medical care could be directly affected by such findings, Institution shall provide to Study participants a written communication of such information.

Such notices of the parties shall be given as follows:

To Institution:

The University of Texas Health Science Center at San Antonio
Office of Clinical Research
7703 Floyd Curl Drive, MSC 7761
San Antonio, TX 78229-3900

With a copy to the Principal Investigator at:

The University of Texas Health Science Center at San Antonio
(Insert PI Name)
7703 Floyd Curl Drive, MSC (Insert PI Mail Code)
San Antonio, TX 78229-3900

To Sponsor:

(Insert Sponsor Name & Address)

7. GENERAL INFORMATION

7.1 This Agreement, including the attached Exhibits A and B, constitutes the entire and only Agreement between the parties relating to the Study, and all prior negotiations, representations, agreements, and understandings are superseded hereby. No agreements altering or supplementing the terms may be made except by a written document signed by the duly authorized representatives of the parties.

7.2 Any conflicts between the Protocol and this Agreement are controlled by this Agreement.

7.3 This Agreement shall be construed and enforced in accordance with the laws of the State of Texas.

7.4 This Agreement anticipates educational training and may involve health science postgraduates and other students of the Institution.

7.5 INSTITUTION MAKES NO REPRESENTATIONS OR WARRANTIES, EXPRESS OR IMPLIED, REGARDING ITS PERFORMANCE UNDER THIS AGREEMENT, INCLUDING BUT NOT LIMITED TO, THE MARKETABILITY, USE OR FITNESS FOR ANY PARTICULAR PURPOSE OF THE RESULTS DEVELOPED PURSUANT TO THIS AGREEMENT. FURTHER, IT IS UNDERSTOOD THAT INSTITUTION SHALL NOT BE LIABLE FOR SPECIAL, CONSEQUENTIAL, OR INCIDENTAL DAMAGES, AS A RESULT OF SPONSOR'S USE OF ANY TECHNICAL REPORT OR RESEARCH RESULTS PROVIDED UNDER THIS AGREEMENT.

7.6 The parties acknowledge that Institution and System are agencies of the State of Texas and under the Constitution and laws of the State of Texas possess certain rights and privileges and only have such authority as is granted to them under the Constitution and laws of the State of Texas. Nothing in this Agreement is intended to be, nor will it be construed to be, a waiver of the sovereign immunity of the State of Texas or a prospective waiver or restriction of any of the rights, remedies, claims, and privileges of the State of Texas.

8. GENERAL NOTICES

8.1 Except as outlined in Article 6 above, all other notices given hereunder shall be in writing and shall be delivered by hand, facsimile, certified or registered mail, or overnight delivery by a nationally recognized carrier, addressed to the parties as follows:

To Institution:

The University of Texas Health Science Center at San Antonio
Office of Sponsored Programs
7703 Floyd Curl Drive, MSC 7828
San Antonio, TX 78229-3900

To Sponsor:

(Insert Sponsor Name & Address)

IN WITNESS WHEREOF, the parties hereto have executed this Agreement by proper persons duly authorized.

(SPONSOR)

By: _____
Name: _____
Title: _____

Date: _____

The University of Texas Health Science Center at San Antonio

By:_____
Chris G. Green, CPA
Senior Director, Sponsored Programs

Date:
_____

I have read this Agreement and understand my obligations hereunder.

By _____
(Principal Investigator)
(Principal Investigator Title)

APPENDIX M

Intentionally left blank