

FACULTY GUIDE TO SPONSORED PROJECTS

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1. PURPOSE AND SCOPE

- A. This policy defines the various types of research support instruments or awards received by the School. It provides the School policy regarding formal review and approval of applications and proposals made by faculty and trainees to outside institutions for research support.
- B. This policy is complementary to "Administration of Research and Training Grants or Contracts" (Section VII, pp.14) and to "Guidelines for Academic-Business Relationships" (Section VII, pp.33) in this Handbook.

2. BACKGROUND

The traditional form of research support (and the most prevalent at WFUSM) is the federal research grant. The most common form of industry-sponsored research is the controlled clinical trial. Other forms are Government cooperative agreements and research contracts, foundation and association awards, and industry supported basic research. Therefore, it is important for faculty to understand the characteristics of various award mechanisms, and the obligations inherent in each. It is also important to obtain the proper institutional sanction for all extramural research proposals, regardless of the organization to which they are directed.

3. DEFINITIONS

- A. Research: Scholarly or scientific systematic investigation or inquiry, designed to contribute to generalizable knowledge.
 - 1. Basic research: Research that provides fundamental knowledge. It is long-term in nature, unlikely to lead to specific applications, and is undertaken for the sake of increasing knowledge.
 - 2. Applied research: Scientific activity directed at solving specific practical problems and generally undertaken with hopes for commercialization.
 - 3. Clinical research: Research involving living humans or human tissues.
 - 4. Development: The resolution of technical problems associated with transforming research into usable products and processes.
- B. Training: Training of students at the pre-doctoral or post-doctoral level in the skills and knowledge necessary to perform research in a specific field of science, or using specific technologies as research tools.

Research training is supported either by institutional grants or by grants or awards to individuals in the form of fellowships.

- C. Agreement: Specifically, a research agreement is a two-party agreement that involves the performance of a specific research project or program by faculty, or under the direction of faculty. Research projects or programs sponsored under research agreements usually involve research with specific and clearly defined goals and objectives. Examples are testing a specific hypothesis, or investigating a drug or device according to an established protocol.

Research agreements are written between institutions (the School and a sponsor). They identify the obligations and interests of each party.

Subcontracts are agreements used when the School is sponsoring research at other institutions. This situation occurs when the School is the recipient of support to direct and manage a multi-institutional collaborative study. In other circumstances, an institution must rely on our faculty to provide expertise or services not available internally (see F below).

Research agreements are generally used when the sponsor desires accountability for the scientific results or a degree of control over the conduct of research. Sponsors usually include:

1. Agencies of the Federal government using research contracts. Federal research contracts are also subject to the policies and procedures included in Section VII, pp. . However, they are similar in substance to research agreements sponsored by other organizations;
 2. For-profit organizations, including companies engaged in the production and sale of goods and services, and companies involved in research and development;
 3. Agencies of the state government; and
 4. Not-for-profit research organizations which require unique expertise or facilities available at the School.
- D. Contract: Research contracts are agreements as defined above. Often contracts include a number of restrictions defined by the sponsor:
1. The award may be subject to formal conditions outlined in the agreement instrument signed by both parties.
 2. The sponsor may place restrictions upon expenditures allowed in the pursuit of the activity (e.g., purchase of equipment, travel, etc.).
 3. Financing may be on a cost-reimbursable basis. Although the School tries to arrange some method of advance funding where possible, some fixed-price contracts may provide for lump sum payments as work progresses.

4. The sponsor may require periodic progress reports, often including invention reports, royalty reports, financial status reports, equipment inventory reports, etc.
5. A closing audit is usually required.

Contracts with agencies of the federal government are governed by a complex body of law codified as the "Federal Acquisition Regulations" (Title 48, Code of Federal Regulations). These regulations include detailed restrictions on activity by institutions competing for contract awards and individual employees of these institutions. Institutions and individuals cannot discuss employment with government officials involved in the award of a contract, offer any government official anything of value, or seek "insider" information. The procedures for compliance are complex and often changing. The current information on the Federal Acquisition Regulations is available through the Controller's Office.

- E. Cooperative agreement: The cooperative agreement is a research agreement used by the federal agencies when the agency staff wish to participate actively in the direction of the research, helping to set goals, objectives, etc. The cooperative agreement often has the same provisions for financial accountability as a grant (Par. G below), and the scientific constraints and definitions similar to a contract (Par. D. above). Cooperative agreements are used almost exclusively by federal agencies, although many state program "grants" resemble cooperative agreements in their intent and provisions.
- F. Consortium agreement: This is an agreement between the School and another organization to support an investigator-initiated research project or program involving staff from both the School and the other organization. Either the School or the other organization may be the principal recipient of support. If the School is the principal recipient, the other organization becomes a "sub-contractor."

Other organizations may include:

1. Educational institutions
 2. Not-for-profit research organizations (e.g., Research Triangle Institute)
 3. For-profit corporations
 4. Federal or Federally-funded laboratories (e.g., NIH or Oak Ridge National Laboratory)
- G. Grant: A grant is an assistance award for research or training when the sponsor has determined that the project is meritorious and makes an award relatively free of scientific restrictions and accountability. Grants are awarded in response to a

proposal or application developed and initiated by faculty. In general, the following criteria identify a grant:

1. The award may carry terms on the use of funds such as specified budgetary restrictions; the general objectives to be achieved by the use of the funds; the individuals responsible for the completion of the work; the period of performance; and invention rights.
2. The sponsor may retain authority to withhold funds pending satisfactory completion of project objectives. The sponsor may require that unused funds be returned.
3. Financial accounting during the life of the project, at its termination, or both may be required.
4. Reports related to the substance of the work, during the life of the project or at its termination, may be required by the sponsor. Copies of published materials may also be requested.
5. Periodic payments are to be made to the School so that the financing of a project is on a continuous basis.

Sponsors of grants include the following organizations:

Agencies of the Federal Government
Agencies of the State Government
Private foundations
Voluntary organizations
For-profit corporations

H. Gifts: A gift is a research or training award with only rudimentary or general restrictions as to its use. Gifts are donations made to the School with general restrictions as to use, and often no specific requirements for scientific or financial accountability. In general, the following criteria identify a gift:

1. Contractual requirements are not imposed. Restrictions by donors are normally limited to specifying general areas of use (i.e., within a general field of research or a specific department).
2. The award is irrevocable.
3. A period of performance is not specified.
4. Financial accounting is not required and there is no requirement to return unexpended funds. However, a report to the donor on the utilization and/or impact of the gift may be requested. Even if the donor does not

request a report, it is School policy that progress reports and terminal reports be sent to the donor unless the donor specifically requests that no report be made.

Donors may include:

1. Individuals or families
2. Private foundations
3. Voluntary organizations
4. For-profit corporations

4. POLICIES

A. All proposals or applications for research support will be signed by the investigator, and will be reviewed and cleared by the investigator's Department Chair, and by the School administration including the following offices:

1. The Controller's Office (unless there is no budget)
2. The Cancer Center (for cancer-related projects)
3. The General Clinical Research Center for proposals utilizing these facilities.
4. The Office of Development and Alumni Affairs for proposals to foundations or individuals not in response to a competitive solicitation
5. The Office of Research

No proposal or application can be considered sanctioned by the School until this clearance is completed.

B. Proposals or applications for research support usually require a detailed budget. It is School policy to request that sponsors support full costs of research including faculty effort and other direct and indirect costs. The School's policy is to request full indirect costs of all sponsors. Full indirect costs are defined as follows:

For all research and demonstration projects
except clinical trials of drugs and devices:

The current rate approved for
Federal awards.

For industry projects, e.g. clinical trials:

The current rate approved for industry.

For training projects:

The current rate approved for Federal awards.

Faculty are cautioned that unless other arrangements are made at the time the proposal is reviewed or at the time the award is negotiated, indirect costs will be assessed from the award at the appropriate rate. When preparing proposals, current rates must be used.

- C. All research agreements will be executed for the School by officers to whom proper authority has been delegated. Agreements executed by individual investigators cannot bind the School to assure performance or to provide appropriate legal protections for the investigator. The following officers are authorized to execute research agreements for the School:

The Vice President and Dean

or

The Senior Associate Dean (Science and Technology)

or

The Associate Dean for Research

or

The Director of Sponsored Research

- D. All sponsored research programs or projects at the School must be supported by a written instrument. Examples of written instruments include notices of award, letters, contracts or other two-party agreements, all of which include at least the following information:

1. Brief descriptive title of the project
2. The duration of the project (project period)
3. The duration for which funding is provided (if different from the project period)
4. The amount of funding provided

4. ADMINISTRATION OF RESEARCH AND TRAINING GRANTS OR CONTRACTS*

A. General Principles

1. Policies of the school that relate to the acceptance of funds from any source recognize two major responsibilities of the institution:
 - a. Assurance to the donor that funds will be used and accounted for in accord with the purposes of the gift, grant or contract and policies set forth by the donor.
 - b. Assurance to the faculty that the necessary flexibility and freedom required for creative research and scholarship be maintained. This includes the freedom to publish any results of research. The school will not accept gifts, grants or contracts with stipulations that preclude the carrying out of these responsibilities.
2. Expenditures of funds are judged by the same standard regardless of the source of funds.
3. The chairman of each department or an authorized representative is responsible for the academic and professional activities of the staff, programs, and total budget of the department. Every effort will be made to continue responsibility for decision making in these areas within this framework. However, it is recognized that final decisions regarding the proper use of and accountability for institutional funds must be the responsibility of the School administration. Administrative support is available to the faculty to help meet institutional requirements for the expenditure of funds as well as those specified by donors of gifts and grants.

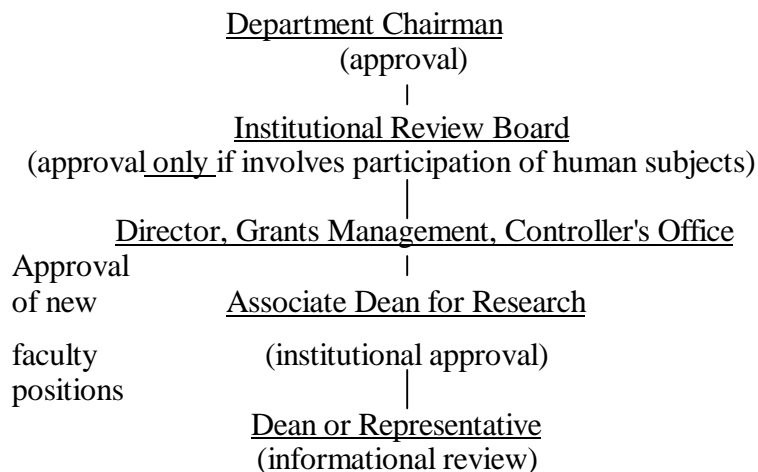
* By definition, training grants shall include all those designated for research training, graduate and undergraduate teaching or training, and faculty fellowship or investigator awards.

B. Procedure for Institutional Review of Grants or Contracts for Research, Teaching or Training Grants, and Faculty Fellowship or Investigator Awards

Principal Investigator

Consultation Services

- a. Associate Dean for Research - assistance in preparation and evaluation of applications and interpretation of institutional and agency policies
- b. Director of Foundation Relations, Office of Development and Alumni Affairs - sources of extramural support
- c. Directors of Research Cores - appropriate charges, services available, animal space requirements
- d. Director, Grants Management, Controller's Office - fiscal policy, budget preparation and management
- e. Purchasing Agent - equipment and supplies
- f. Department Chairman/Dean and Vice President - must approve if proposal involves new faculty, additional space, or renovation.



Notes on Review Procedures

1. Kits containing instructions and forms for applications to the National Institutes of Health may be obtained from the Office of Research or on the Office of Research website.
2. Investigators are urged to take full advantage of the consultation services available. It is recommended that investigators consult with the Associate Dean for Research or the Director of Sponsored Research concerning the narrative portion of the application when copy is in semi-final stage (before typing on agency forms). If laboratory animals are to be used, the Director of the Animal Resources Program should be consulted concerning animal space requirements and costs of procurement and maintenance of animals. Realistic budget figures for computer services, biomedical engineering, and audiovisual resources should be obtained from the appropriate Director. A full list of all equipment items and major or unusual supply items should be submitted to the Purchasing Agent to obtain realistic price information.
3. The front sheet (face page) of all grant applications must be initialed in ink by the department chairman or an authorized representative. This signifies that the grant has been reviewed in terms of the objectives of the department and its programs and:
 - a. The project is sound, well presented, and likely to be approved by the agency or foundation to which it will be submitted.
 - b. The objectives are likely to be achieved in the stated time.
 - c. The budget is realistic and items are deemed essential to the successful prosecution of the project. In the case of equipment requested, no similar equipment is available or suitable for use. Salaries for non-faculty personnel are consistent with institutional ranges for persons with similar qualifications, experience and responsibilities.
 - d. The project can be conducted in presently allocated space (unless alteration or new space has been previously approved by the Dean).
 - e. The percent of effort committed to the project by the personnel indicated is realistic and will not jeopardize other expected duties and responsibilities of the individuals involved.
4. Modified procedure for requests for Intramural Research Support funds: guidelines for preparation of applications may be obtained from the Office of Research or the Office of Research website. After approval by the Department Chairman, applications are sent directly to the Office of Research.

5. If human subjects are involved in the proposal, the "Protocol Review Form" of the Institutional Review Board (obtained from the Office of Research or the Office of Research website) must be completed. The Institutional Review Board is described in Federal regulations, and all applications must conform to the regulations concerning protection of human subjects.
6. If live vertebrate animals are involved, the following statement should appear at the end of the application: "The animal facilities of The Wake Forest University School of Medicine are fully accredited by the Association for Assessment and Accreditation of Laboratory Animal Care, International (AAALAC, Int.)."
7. Deadlines - In order to allow a satisfactory institutional study, all applications must begin the review process at the level of the department chairman at least 10 working days prior to the deadline of the agency or foundation concerned.

C. Specific Policies Related to Grants

1. Professional salaries

- a. Professional salaries are established in consultation with the Dean and Department Chairman concerned. They shall be consistent with institutional standards for persons with similar qualifications, training, experience, rank, etc.
- b. When a person receives salary from a grant, the pro rated amounts may not exceed the percent of effort expended by the individual on the project. Faculty members shall apply for salary support commensurate with the time and effort related to grant activity.
- c. Charges against a grant award will be made in accordance with the approved grant budget and the annual assignment of percent of effort to the project. Effort reports will be reviewed by the department chairman. If it should become apparent that the total effort for the grant budget period will fall below the level specified in the current budget, the investigator must notify the department chairman and the Associate Dean for Research promptly so that appropriate budget or effort revisions may be made. Notification of revision of effort percentage is required even if no salary is derived from the grant. A description of the procedure for estimating effort appears on the next two pages.
- d. Retroactive transfer of salaries between grants is not allowed unless required by a change in effort assignment and approved after administrative review.

2. Non-faculty salaries

Salaries must be consistent with institutional standards for persons with similar qualifications, training and experience. Retroactive transfer of salaries between grants is not allowed.

3. Equipment

Equipment is defined as any item with a useful life of 2 years and costing >\$3500 or more, whether as a single purchase or fabricated with components of lesser value. All equipment purchased under any research or training grant or contract is the property of the school, unless a special agreement concerning equipment has been made by the school administration with the granting agency. School policies apply to all equipment, regardless of the source of purchase funds.

a. Equipment will be purchased only after it has been determined that no other equipment is available or suitable for the intended use. This determination should be made by the principal investigator before the purchase requisition is initiated by contacting the property control officer. Available means that the required item is available when needed and in good working order.

b. In order to comply fully with the regulations of the National Institutes of Health, an inventory of major scientific equipment is maintained by the Property Control Office. When an item of equipment is no longer required by the project for which it was purchased, the Property Control Office and the Office of Research must be notified. If it is known that the equipment item is needed on another project, a request may be made for reassignment of equipment, the Associate Dean for Research may reassign the equipment to any project requiring such equipment. Our equipment inventory specifies the location of equipment by room number or research project area. If equipment items are to be transferred to another part of the school, either on loan or on reassignment to another project, the Property Control Office must be advised of the new location by memorandum.

Title to equipment items may be transferred to another institution in accordance with the policies on "accountability" for equipment of the granting agency. In general, only specialized items of equipment not suitable for other use within this institution will be transferred with an investigator to another institution. All transfers of title must be approved and executed by the Associate Dean for Research or other authorized representative of the Dean.

Used items of equipment may be traded in on new equipment items under certain circumstances in accordance with applicable regulations on "accountability" of the granting agency. The Associate Dean for Research should be consulted in advance concerning applicable regulations, and must approve in writing any trade-in proposal. Negotiations with vendors concerning trade-in allowances must be conducted by the Purchasing Agent.

No item of equipment on inventory may be discarded or otherwise disposed of without approval of the Property Control Office. In general, items that are no longer usable and have a depreciated value of less than \$50.00 may be removed from the inventory list by the Property Control Office.

c. Purchase orders. Prior approval (see #5 below) must be obtained in advance of issue of purchase order for any equipment items not specified in the approved grant

budget. Purchase orders for routine supplies may be signed by the principal investigator or an authorized representative.

d. Authorized representatives shall be designated by the principal investigator to the Controller. This authorization will be maintained in the file on each grant.

4. Expenditures for Central Research Services

It is assumed that the amount of funds identified in the grant application for research services are necessary to the successful prosecution of the project. As such they should be indicators to the director of each service department in anticipating budget requirements for personnel, supplies, etc. If anticipated income does not materialize, excessive personnel costs and inventories result in deficits that must be made up in some way by basic school funds. Because of this situation and to meet requirements of granting agencies, Prior Approval (see #5 below) must be obtained for transfer of funds from a research service category to any other purpose.

5. Prior Approval for Grant Budget Changes as Provided By:

NIH -- Institutional Prior Approval System (IPAS)

and

NSF -- Organization Prior Approval System (OPAS)

This school has received authority delegated from the NIH and the NSF to review and approve certain requests relating to rebudgeting and expenditures arising in connection with performance under awarded grants. Each request must be prepared in advance of the anticipated need and follow the procedure described below.

A request must be initiated by the Principal Investigator or Program Director by memorandum directed to the Associate Dean for Research. It is essential that the request be made prior to commitment of funds or issue of purchase order. The memorandum should emphasize the scientific justification of the change requested and should treat adequately all of the following points that are applicable to the request:

- Exact nature of expenditure requested, with itemized cost estimate.
- Budget categories to be altered by requested change (e.g., transfer of \$2600 from Supplies and \$1500 from Personnel to Equipment).
- The scientific need for the requested expenditure in relation to the aims and objectives of the approved grant application.

- Any significant effect the proposed budgetary change might have on the general scientific or educational direction of the project.
- Equipment: Statement of the scientific reason for need of the equipment in relation to the aims and objectives of the approved grant application.
- Domestic travel exceeding the amount specified in the award notice and foreign travel: demonstration that the proposed travel will provide direct benefit to the project (the general desirability of attending meetings is insufficient justification).

Each request for budget changes will be reviewed for scientific and procedural propriety by the Associate Dean for Research and the Controller. If the request is approved, a memorandum to the file record of the grant will be issued, and a copy supplied to the Principal Investigator or Program Director and Department/Section Head. Purchase orders may be issued only after receipt of the memorandum authorizing the budget change.

<u>Types of Expenditure</u>	<u>Approval Authority Delegated to WFUSM</u>	
	<u>NIH</u>	
<u>NSF</u>		
Rebudgeting from one category to another	yes	yes
Alterations and renovation \$10,000	LT \$25,000*	LT
Motion picture, video tape production, etc.	LT \$25,001	yes
Contracts for project effort	no	yes
Equipment		
General Purpose	LT \$25,001	no
Special Purpose	LT \$25,001	yes
Substitution of approved item by unapproved item	yes	yes
Allocate funds among closely related grants	no	yes
Hiring consultants not previously authorized	yes	yes
No-cost extension of project period and carryover of Funds (R-type awards) up to 12 months	yes	yes
Pre-award costs (up to 90 days)	yes	yes

Travel – Domestic (when not included or exceeds amount)	yes	yes
Travel – foreign	yes	yes

*Subject to some restrictions

Examples of expenditures for which authority has NOT been delegated to WFUSM by NIH or NSF.

- Restrictions imposed by Notice of Grant Award.
- Any item proposed in grant application that the initial review group or agency staff removed from approved budget.
- Change in principal investigator.
- Change in scope of project.
- Trainee stipends (other than among stipends and tuition and fees).
- Change in grantee institution.
- Extension of project period after institutionally approved extension.
- Patient care costs when the need was not previously approved, or to rebudget funds from the patient care category.
- Retroactive prior approval.

6. Time/Effort Assignment and Effort Reports

Effective planning of academic programs requires that there be a definite understanding of the commitment of each faculty member to major areas of program responsibility. Assignment and reporting of effort is also a legal requirement for any program supported directly or indirectly by Federal funds. The following procedures are in use:

a. Non-Faculty

Time and attendance records are required to be maintained for all employees who do not have faculty rank (clerical, technicians, etc.). At the end of each pay period, the record is signed by the responsible individual and sent to Payroll in support of payroll records.

A time/attendance record is required by Wage and Hour Law and various other Federal agencies. It is likewise essential for determining vacation and sick leave due.

The accuracy of these records is most important. An after the fact certification of project-paid personnel is required for each 2 pay period (monthly) cycles. It is important that changes in project effort be made promptly in the payroll system.

b. Faculty

- (1) New Faculty. Upon appointment to the faculty, each new faculty member will have a written agreement with the department chairman concerning the assignment of the total professional effort to the various program areas of the department (e.g., 10% teaching, 30% research, 60% patient care). This agreement must be approved by the Dean.
- (2) Annual Effort Assignment. There will be annual review of the effort assignment of each faculty member, and changes may be made as required by program changes. Effort assignments for the fiscal year will be reviewed and affirmed during the annual budget conference between the Dean and each department chairman.
- (3) Annual Effort Report. At the end of each academic term, each faculty member is required to complete a form that will specify the best estimate of the division of total professional effort for the year among the various programs. The total effort estimate is first apportioned among the major areas (teaching, research, service responsibilities). It is recognized that this report represents an estimate, based on the best judgment of the faculty member, and is not an exact time log. Consideration should be given to all professional activities, whether on-campus or off-campus, and whether during the usual working hours or at other times. Effort expended in preparation for teaching, in planning or thinking about research activities, or in attendance at professional meetings should be given due attention. Effort is not necessarily equivalent to time, as some activities are more demanding than others. A "best judgment" estimate of effort is what is expected.