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VIII. RESEARCH ADMINISTRATION

Overview

The Kansas Board of Regents has established research as a major mission for the University of Kansas. The Board has delegated the authority (KSA76-723) for oversight of all research programs and the conducting of all research to The Chancellor of the University of Kansas and the Executive Vice Chancellor of the University of Kansas Medical Center (KUMC). At the KUMC, the Executive Vice Chancellor (EVC) has allocated basic responsibilities related to research in the following ways.

- The University of Kansas Medical Center Research Institute, (Research Institute) a not-for-profit University corporation <http://www2.kumc.edu/researchinstitute>, has responsibility for Research Administration.
- Deans of the School of Medicine, School of Allied Health, and School of Nursing are responsible for conducting the program of research and for collaborative research centers and core research service facilities. <http://www.kumc.edu/som/research.html>; <http://www.kumc.edu/allied/research.html>; <http://www2.kumc.edu/son/research.html>
- The KUMC Research Compliance Division. <http://www2.kumc.edu/researchcompliance> has responsibility for overseeing a comprehensive research compliance program.
- The Research Advisory Council (RAC) <http://www.kumc.edu/rac>, has responsibility for providing formal counsel and advice on research matters to the Executive Vice Chancellor. The RAC consists of research representatives from each of the three schools with an additional School of Medicine representative from the Wichita campus. The KUMC Faculty Assembly http://www2.kumc.edu/aa/fa/fac_assembly.htm is represented on the RAC by the Chair of the Faculty Assembly Research Committee (FARC). The basic mission of the RAC is to review research-related issues for the entire research mission of the Medical Center and advise the EVC.

University of Kansas Medical Center Research Institute, Inc.

The KUMC Research Institute, <http://www2.kumc.edu/researchinstitute> is a not-for-profit 501 (c) (3) corporation that performs the administrative services related to extramural grants and contracts for all KUMC faculty and staff. This responsibility includes all pre- and post-award functions, clinical research support, contract development, technology transfer, and intellectual property issues related to faculty and staff inventions. As President of the Research Institute, the Executive Vice Chancellor is the authorized agent for all new and continuing research grants and contracts. The Research Institute President and the Research Institute Executive Director/ Vice Chancellor are authorized to review and approve KUMC grant and contract proposals for the University. They are also responsible for negotiating and administering all related agreements. The Research Institute Board of Directors consists of seven University administrators, five faculty and eleven members of the Kansas City community. http://www2.kumc.edu/researchinstitute/admin/committees_list.html.

The Executive Director of the Research Institute also serves as Vice Chancellor for Research Administration, acts as an advocate for the research community to the administration, and serves as a liaison between faculty and outside funding agencies.

Among the research-related activities of the Research Institute are:

- Institutional approval of applications for external funding of research and sponsored programs;
- Negotiation of the applications prior to award;
- Institutional administration of both pre-award and post-award services for grants/contracts/other sponsored programs;
- Communication of funding opportunities to all faculty on a regular basis;
- Staff assistance to the FARC and the RAC <http://www.kumc.edu/rac>.
- Coordination with the Department Chairs and Deans of the three schools to support research plans for the future;
- Administration of internal funding to enhance the research developmental activities of the departments.

The Research Institute has assigned responsibilities to the Wichita campus for certain pre-award functions (see IIIA) and for management of clinical research (see I).

Office of the Vice Chancellor for Research Administration

The Vice Chancellor for Research Administration is designated as the KUMC official responsible for research administration.

Any written communication made by the Principle Investigator (P. I.) to the funding agency concerning the administration of the award (i.e., rebudgeting, change of effort or thrust, change of P. I., extension of funding period, etc.) must be countersigned by the Vice Chancellor for Research Administration. This requirement is established by the funding agencies because awards are made to the Institution(s).

The Vice Chancellor for Research Administration is also designated as the official authorized to conduct expanded authority privileges of various funding sources. (Forms are available from the Division of Sponsored Programs Administration and the Office of Research – Wichita.

Principal Investigator (P I) or Project Director

All faculty may exercise the privilege of being named as P. I. or Project Director on proposals submitted for external support. Unclassified professional staff may qualify to serve as P. I.; however, justification to designate a person other than a faculty member as principal investigator must be approved by the appropriate Chair, Dean, and Vice Chancellor for Research Administration prior to submission of a proposal for external funding. The P. I. is responsible for compliance with all the specific requirements of the sponsoring agency and the KUMC.

In all cases, institutional approval must be obtained prior to the submission of the application to the funding agency, as outlined in Policies and Procedures for External Funding of Research and Sponsored Programs (*in this section*).

Facility and Administrative Overhead (indirect costs)

Policy: The Vice Chancellor for Research Administration is responsible for ensuring that appropriate F&A costs have been included in every proposal.

Facility and administrative overhead revenue plays a vital role in the administration and conduct of research and sponsored programs. It is awarded as a means of offsetting a portion of the expenses inherent in the operation of an organization and the performance of its programs. These expenses include such items as plant operations, maintenance, accounting and administration, core facilities and services (safety operations, library, etc.) and general and departmental administration. Therefore, it is important that these costs be included on all grants and contracts unless specifically prohibited by the funding source as a condition of the award. Most federal and nonfederal funding agencies allow a stipulated rate for calculating these costs.

Federal rates are negotiated and information concerning the current rates, base, and the date of agreement is available in the Sponsored Program Administration Office and Office of Research – Wichita. http://www2.kumc.edu/researchinstitute/spa/SPA_Forms/Rate_Agreement_07-09-02.pdf

Unless the funding source specifically excludes such expenses for the grant program, the P. I. must include such expenses as a line item in the proposed budget. In some cases, funding agencies will allow a direct cost for administrative overhead rather than indirect costs. If this is the case, the P. I. must include this cost.

The Research Institute has four administrative divisions.

- I. The Division of Clinical Research Administration
- II. The Division of Finance and Administrative Services
- III. The Division of Sponsored Programs Administration
- VI. The Division of Technology Transfer and Intellectual Property

I. The Division of Clinical Research Administration

Policy: All extramurally funded clinical research for KUMC faculty must be managed by the University Of Kansas Medical Center Research Institute. For clinical trials research on the Wichita campus, the Vice Chancellor for Research Administration has delegated this responsibility to the Dean of the School of Medicine at Wichita.

The Research Institute's Division of Clinical Research Administration assists faculty and clinical staff in all service aspects for: marketing for new clinical research; pre-award

contracts, financial, human subjects approval; post award monitoring; quality assurance in the clinical research setting; in-service education and study closures. Complete procedures and additional information can be found on the web page. <http://www2.kumc.edu/researchinstitute/cra/index.html>.

II. Division of Finance and Administrative Services

<http://www2.kumc.edu/researchinstitute/fas/index.html>

The Division of Finance and Administrative Services is responsible to manage all funds provided by extramural research grants and contracts, develop and manage the operating budgets of the Research Institute, oversee all accounting functions for the Research Institute and related entities, operate a Human Resource Office for Research Institute employees, and oversee all properties owned or leased by the Research Institute.

The Executive Vice Chancellor, as President of the Research Institute, the Vice Chancellor for Research Administration/Executive Director of the Research Institute and the Chief Financial Officer of the Research Institute are responsible for all functions of this Division.

III. The Division of Sponsored Programs Administration

Policy: All proposals and applications for research or sponsored programs (new, competing renewals, non competing, fellowships, etc.) including grant proposals, material transfer agreements, consulting agreements or contract proposals submitted to an outside agency by KUMC faculty or approved unclassified or professional staff, must be processed through the Research Institute for institutional approval prior to submission to funding agencies.

The Division of Sponsored Program Administration has two major functions. The first is assisting faculty in the proposal development process (Proposal Development Office). The second is monitoring grant expenditures when awarded (Grant Monitoring Office).

A. Proposal Development Office (Pre-award)

<http://www2.kumc.edu/researchinstitute/spa/spaproprocess.html>

Kansas City Campus: The Proposal Development Office is authorized to assist faculty in the submission and negotiation of all proposals for new or continued federal and private support of University projects. The Executive Vice Chancellor and the Vice Chancellor for Research Administration are authorized to review and approve such proposals for the KUMC. They are responsible for negotiating and administering the agreements.

Wichita Campus: The Dean of the School of Medicine-Wichita is authorized by the Vice Chancellor to review and sign proposal applications prepared by faculty on that campus. The Wichita Research Office <http://wichita.kumc.edu/research> coordinates the submission of proposals with the Kansas City office. All grant awards and research contracts must be signed by the Vice Chancellor for Research Administration as certification of institution final acceptance.

Procedures for proposal development

The following procedures for processing proposals for external funding of research and sponsored programs (training, fellowships, service, drug protocols, etc.), and for administration of the award (grant, contract, cooperative agreement, or gift) apply to both Federal and non-Federal applications:

Policies and procedures for preparing an application for external funds vary among funding agencies. The Proposal Development Office of the Research Institute and the Office of Research in Wichita provide services to assist faculty in developing proposals.

An Institutional Application Checklist http://www2.kumc.edu/researchinstitute/spa/SPA_Forms/SPA_FY03_Checklist_11-11-03.pdf must be completed for all applications for external funds whether for research, service, training or other external support. This checklist is a management tool to ensure the review and approval of the application at the department, school, and administrative levels. If the P. I. and co-investigator are in different Departments, Schools and/or Centers, the signatures of all Chairs, Deans, and/or Center Directors are required.

Signature Approvals

1. Department(s) approval indicates that:
 - a. The project is consistent with the overall objectives of the department, represents high quality research, and has substantial scientific merit.
 - b. Adequate (co)investigator time is available to conduct the project and the time committed is consistent with the terms under which the (co) investigator is employed.
 - c. Adequate research space and facilities are available within the department(s) to support the proposed project.
 - d. Requests for new equipment have been reviewed to determine whether similar suitable equipment might be available in the department(s) or school(s).
 - e. Matching funds and resources are available.
2. Center for interdisciplinary concentration approval indicates that the Center Director has reviewed and approved commitments or requirements of the individual center involved.
3. School approval indicates that:
 - a. The project is consistent with the mission of the school(s).
 - b. The commitment of school resources is consistent with the mission of the school.
 - c. New positions would be available if the project is awarded.
 - d. The School will guarantee any matching funds.

4. Administrative approval indicates that:
 - a. All department and school approvals have been obtained.
 - b. The budget (direct and indirect costs) is appropriate and that equipment items are justified.
 - c. Facilities and services required will be available when the project is awarded and that costs requested are adequate to cover the services required. Such services include: mathematical and statistical services; computer-related services; hospital services, facilities and personnel; animal care services; electron microscopy services; and other core or institutional services.
 - d. Space requirements have been addressed.
 - e. New faculty positions would be available if the project is awarded.
 - f. Project applications involving the use of human subjects have been submitted to the Human Subjects Committee (HSC), Kansas City - <http://www2.kumc.edu/researchcompliance/human.htm> and Wichita - <http://wichita.kumc.edu/research/humanSubjects.html> in accordance with KUMC policies and sponsor-specific mandates and pre-award approvals have been obtained when required by the University or the granting sponsor.
 - g. Project applications involving the use of animals have been submitted to the Institutional Animal Care and Use Committee (IACUC) <http://www.kumc.edu/lar/acupform.html> in accordance with KUMC policies and sponsor-specific mandates and pre-award approvals are obtained when required by the University or the sponsor.
 - h. A biohazard form <http://www2.kumc.edu/researchcompliance/forms/researchsafety.pdf> has been submitted to the Institutional Research Safety Committee (IRSC) <http://www2.kumc.edu/researchcompliance/irsc.htm> for all applications and that projects involving Class II, III or IV biohazard risks have been approved by the IRSC.
 - i. Project applications involving the use of radioactive material have been submitted to the Radiation Safety Committee (RSC) http://www2.kumc.edu/safety/policies/RadManuals/University_Rad_Safety_Manual.pdf in accordance with University policies and pre-award approvals are obtained when required by the University.
 - j. Applications are complete, conform to funding agency guidelines, and are accurate in terms of forms and budget.
 - k. Conflict of Interest Forms http://www2.kumc.edu/researchcompliance/forms/COI_2004.pdf have been submitted for all related grant personnel, reviewed and approved by the department chair or center director, and received by the Research Compliance Division, in accordance with KUMC policies and procedures governing conflict of interest <http://www2.kumc.edu/researchcompliance/coikumcpolicies.htm>.
 - l. HIPPA forms <http://www.kumc.edu/hipaa> have been submitted for all applications involving protected health information.

B. Grant Monitoring Office of the Sponsored Program Administration
 (Administration of grants and contracts once awarded)

Policy: Although the grant is awarded to the applicant institution (KUMC or KUMC-Research Institute), the principal investigator is responsible for compliance with all the specific requirements of the sponsoring agency upon accepting the award.

The Grant Monitoring Office <http://www2.kumc.edu/researchinstitute/spa> under the direction of the Vice Chancellor for Research Administration is responsible for all special award requirements for Kansas City and Wichita, such as: approval requirements related to budget changes, change in the scope or project objectives, change in the P. I., prohibition in spending against unallowable costs, carryover approval requirements financial reports, limitations on travel, special approval for the purchase of equipment, number of hours to be applied to the project by specific personnel, time and effort reporting, and other related post award matters.

At the time the award document is received, the Grant Monitoring Office will assign an account number, which is to be used on all financial transactions. The financial billing or reporting date is noted and all necessary reports will be prepared as of these dates. The Grant Monitoring Office will be responsible for financial and administrative compliance of all expenditures applied to each award account. It is also responsible for timely submission of the required financial billing and reporting.

State and institutional financial policies require that grant income be used for the purpose for which the income was awarded. As a result, “fund accounting” procedures are utilized and each project must have its own unique account number.

Policy: The Research Institute specifies that expenditures cannot be processed against a grant until funds are secured from the awarding organization.

The Research Institute is not in a position to finance or make arrangements to finance awards for which funding is not secured in advance. Exceptions to this policy should be initiated through the Vice Chancellor for Research Administration. Decisions are made on a case-by-case basis relating to need, assurance of award, funding agency policies regarding pre-award expenditures, etc.

Complete accounting requirements can be found at the Division of Sponsored Programs Administration. Web page. <http://www2.kumc.edu/researchinstitute/spa>

IV. The Division of Technology Transfer and Intellectual Property

Policy: The University of Kansas Medical Center Research Institute, Inc. through its Division of Technology Transfer and Intellectual Property is responsible to manage all technology disclosures and patenting processes for all KUMC faculty and staff research inventions.

Faculty and staff assignment of inventions to the KUMC

As a condition of employment, at the time of employment, all faculty and staff must agree to assign ownership of all newly created inventions (other than textbooks) which are invented on the campus, or as a result of research and other activity originating on the campus to the KUMC. KUMC through the Research Institute Division of Technology Transfer is responsible to assist faculty and staff in disclosure, protection, and commercialization of such inventions. Members of the faculty and staff shall sign the following Agreement at the time of employment.

PATENT AGREEMENT

I, _____, acknowledge, accept, and agree to abide by the statement of patent policy published in the Handbook for Faculty and Other Unclassified Staff of the University of Kansas. More specifically, for the effective implementation of that Patent Policy I agree 1) to report promptly, through the Research Institute, all inventions conceived by me in the course of research and related activities at the University; 2) to abide by the decisions of the advisory committee of the University appointed as provided in said patent policy; 3) to assist the Research Institute or appropriate patent management firm determined by the Research Institute in the prosecution of patent applications on such inventions; 4) to assign to the University of Kansas all right, title, and interest in any patents issued on such inventions. Finally, if I work on a project supported in whole or in part by an external sponsoring agency, I agree to comply with all terms and regulations on patents and inventions prescribed by the agency and accepted by the Research Institute.

I further agree that the term "invention" as used in this Agreement means any process, machine, manufacture, composition of matter or design, or any new or useful improvement thereof, and any variety of plant, which is or may be patentable under the Patent Laws of the United States.

Date _____ Signature _____

Accepted _____

(Sign and return to the University of Kansas Medical Center Transactions Office)

K.S.A. 44-130 provides that this agreement does not apply to an invention for which no equipment, supplies, facility or trade secret information of the employer was used and which was developed entirely on the employee's own time, unless:

- 1. The invention relates directly to the business of the employer or to the Employer's actual or demonstrably anticipated research or development;

Or

- 2. The invention results from any work performed by the employee for the employer.

Please list below all inventions (if any), which you are currently developing. Attach another page, if necessary.

The Board of Regents has established the following policy:

Patents obtained on inventions resulting from institutionally sponsored research shall be retained by the University or may be assigned to an organization (hereinafter called the Organization) independent of the institution and created for the purpose of obtaining patents on inventions, receiving gifts, administering or disposing of such patents, and promoting research at the institution by every proper means. The following regulations shall be followed with respect to patenting inventions:

- (1) *Anyone who conceives an invention resulting from a research project sponsored by the institution shall report the matter to the appropriate research administrator at the institution, who will recommend whether or not to forward it to the Organization.*
- (2) *If the institution or the Organization decides that the invention does not warrant patenting, the inventor is free to patent it. In such a case, however, the institution does not relinquish its right to publish any of the data obtained in the research project.*
- (3) *When any revenue is obtained by or on behalf of the institution from the development or assignment of any patent or from royalties, license fees or other charges based on any patent, not less than twenty-five (25) percent of that revenue shall be paid to the inventor.*
- (4) *The remainder of any revenue mentioned in Paragraph 3 shall be used to sponsor further research and research-related activities in the institution. The institution may agree that the Organization may retain a portion of the funds.*
- (5) *In the case of cooperative research sponsored in part by an outside corporation or individual, a written contract shall be made between the institution and the cooperating agency. This contract should include a statement of policy substantially equivalent to that outlined below:*

"It is agreed by the parties to this contract that all results of experimental work, including inventions, carried on under the direction of the scientific staff of the institution, belong to the institution and to the public and shall be used and controlled so as to produce the greatest benefit to the public. It is understood and such inventions have commercial value, the cooperating agency shall receive preferential consideration as a prospective licensee, with a view to compensating said cooperating agency in part for the assistance rendered in the investigation. "It is further agreed that the name of the institution shall not be used by the cooperating agency in any advertisement, whether with

regard to the cooperative agreement or any other related matter."

- (6) In case of a research project where it is proposed that all costs, including overhead, salary of the investigator, reasonable rent on the use of equipment, etc., are paid by an outside party, the outside party and the institution shall negotiate the appropriate assignment of all patent rights prior to the provision of any funding by the outside party. The institution shall reserve the right to publish all data of fundamental value to science and technology.*
- (7) Changes in the above policies may be made by the institution to conform to the requirements of the United States Government when contracting with the United States Government or a Federal Government Agency.*

Further policies related to royalty distribution, faculty and institutional conflict of interest and student involvement in inventions could be found at the Research Institute web page. <http://www2.kumc.edu/researchinstitute/tech/index.html>

The University of Kansas Medical Center retains the right to a non-exclusive, royalty-free license to practice the technology for educational or research purposes and retains the right to require reimbursement for funds expended in support of the invention before revenue is distributed.

The overriding philosophy that prevails in determinations related to patent prosecution includes the following concerns: effecting benefits to society, recognition of the inventor or originator, the dissemination of the results of each, the honoring of contractual arrangements with grantors, and assuring the University of current and continuing support for its efforts in providing an environment for creative endeavors.

A. Procedures for the Patent Process

All intellectual property is owned by KUMC but is managed through the Research Institute according to the signed agreement between the two parties. The patent process includes the following:

1. Inventor obtains, completes, and returns an Invention Disclosure Statement to the Division of Technology Transfer and Intellectual Property. Under certain circumstances, this Statement may also apply to copyrights; e.g., computer software.
2. As soon as possible, a meeting is scheduled among the inventor(s), the Division Director, and Research Institute Legal Counsel. This initial meeting should determine or shall provide:
 - i. Who the inventors are;
 - ii. Was this done on university time or property;
 - iii. What other institution(s) has an interest;

- iv. General guidelines for division of royalties;
 - v. Status of the patent;
 - vi. Public disclosure status;
 - vii. Funding costs for exploring a patent;
 - viii. If there is another company interested;
 - ix. Provide advice to the inventor on how to proceed, including legal assistance in the reading and evaluation of contracts and legal documents; and
 - x. Written statement from inventors indicating the division of any income, royalties, etc. derived from their invention.
3. Minutes are derived from all meetings and a permanent file, including all subsequent correspondence, is maintained in the Division of Technology Transfer and Intellectual Property. After agreement is reached on all aspects, including the distribution of royalties, the Division Director sends a letter to the Vice Chancellor for Research Administration. A specific financial account is established in the Research Institute Division of Finance and Administrative Services as soon as expenses and or revenue are incurred. Reports of this activity are made available to the inventor(s) and Executive Vice Chancellor of the Medical Center as requested.
 4. Divisions of royalties are made according to the KUMC policy. <http://www.kumc.edu/Pulse/policy/ttrd.html>
 5. In cases where NIH funding is involved, Title 35 of the U.S. Code, Sections 200-212 applies, i.e., the invention is the property of the funded institution, which is the KUMC.
 6. Related KUMC Policies
 - i. Intellectual Property for Faculty
http://www2.kumc.edu/researchinstitute/tech/Inventor_Information.html
 - ii. Conflict of Interest
<http://www.kumc.edu/Pulse/policy/icoi.html>
<http://www.kumc.edu/Pulse/policy/moicoi.html>
<http://www2.kumc.edu/researchcompliance/coi.htm>
 - iii. Distribution of Royalties
<http://www.kumc.edu/Pulse/policy/ttrd.html>

B. Copyright Procedures

Copyrights for textbooks are owned by faculty authors and/or their publishers. Other forms of the expression of ideas (computer software, CD-ROM, wireless communications, workbooks, videotape, distance learning, telemedicine, etc.) will be owned by the University of Kansas Medical Center.

If a project funded partially or completely from contract, grant or other outside sources produces a product where copyright is being considered, the Director shall report this

consideration to the Vice Chancellor for Research Administration. The report is necessary for the following reasons:

The Research Institute is the agent of the University, which represents a sponsored project to the granting agency. It is this legal responsibility that results in the Research Institute's concern for seeing that both the outside agency and the person(s) wishing to copyright are fairly represented.

Different agencies have different policies concerning copyrighting. The Research Institute and the General Counsel of the University can provide necessary information concerning: (1) the differences between agencies with respect to their requirements; (2) information on contracts with publishers where copyrights are involved; and (3) information on copyrighting in general.

Therefore, before any copyright is applied for or before any contract is signed with a publisher that involves a product from a project supported in whole or in part by outside funds, a report must be made to the Research Institute.

Exceptions: The publication of journal articles or single chapters in textbooks is exempt from the above reporting procedures. The production of a textbook or a substantial portion of a textbook where a faculty member is a co-author should be reported. Appropriate credit must always be given when any state, federal, or private funds have been involved.

C. Use of Copyright Material

For general information on the University's position regarding use by its faculty and students of materials copyrighted by others, according to the current copyright law, consult the KUMC Dykes Library. For more specific information, consult the Office of the University General Counsel.

Classified Research

A Statement of Policy on Classified Research at the University of Kansas was approved by the University Senate on October 23, 1969, and is reproduced in full below:

University policy concerning research is derived from the University's basic goals. One such goal is the development of new knowledge, necessarily through research by faculty and students. Another goal is the constant submission of all knowledge, new and old, for reappraisal by anyone concerned. A third goal is the dissemination or teaching of such knowledge as apparently still stands the test of reappraisal, as well as teaching the techniques of reappraisal themselves. And to the extent that the University is a part of the society, which built and maintains it, the security of that society in times of national emergency can be a goal of the University.

The integration of multiple goals traditionally has depended on the exercise of reason and good will within the University community. Thus, the policy which follows states only the general consequences of our multiple goals for the problem of classified research and assumes that specific cases will be fitted to that policy in an open and reasonable manner.

Classified research may be broadly defined as research in which the University accepts from outside some abridgement of the usual requirement that the total procedures, techniques, tools, data, results, and products of the research are open to inspection and appraisal by any legitimately interested person, usually through unrestricted publication by the investigator at such time as he/she deems appropriate. Research may be classified with respect to (1) its primary sources, (2) the process itself, or (3) its product; and the abridgement or classification may be made in the interest of the Government, corporate organizations, or individual persons.

This University will accept no theses, dissertations, research grants, contracts, assignments, or agreements which are classified., The only exceptions to the policy include classification of primary sources, products, processes, or national emergencies.

1. Classification of Primary Sources

Individuals, corporate organizations, and Government agencies are sometimes willing to permit access to private records and to provide personal data for use in research so long as the confidential nature of the materials and the privacy of the individual are respected. In the Humanities, such limitations are often placed upon the use of primary sources, in the Behavioral Sciences on the identity of the subject, in the Engineering Sciences on data furnished by corporate or Government bodies. Such restrictions are acceptable when they are in the best interests of the researchers and the University and the integrity of the investigators and their work is not compromised.

2. Classification of Process

The University will allow the momentary classification of research (not to exceed one year) when this classification is required by outside agencies to protect their interests by preserving the privacy of the data, records, and products generated in the processes of the research, provided such momentary classification is deemed in the interest of the University and all faculty members and students who are involved.

In the case of student research, such classification shall be further limited by the proviso that it shall not restrict in any way the Department and Graduate School in their usual practices of appointing members to the

Student's Advisory Committee, nor the student's freedom to seek expert advice and assistance from the faculty, nor the ability and duty of the members of the Student's Advisory Committee to inspect the research process and product at any time.

3. Classification of Product

This momentary classification may not extend beyond one year after the development of the research result or product, the point of development being judged by the responsible investigator. Such momentary classification may be accepted only when its conditions are approved in writing by the Office of Research Administration and the faculty member concerned.

When students propose to use the research for a thesis or dissertation or other requirement of a graduate enrollment, such classification shall be further limited by the proviso that, (a) theses and dissertations performed as part of such research will be unclassified, or else will not be submitted to the committee, for formal defense, until they are declassified, i.e., until their procedures, techniques, tools, data, and results are open to inspection by any member of the Graduate Faculty; and (b) the conditions must be approved in writing by the Graduate School, the students involved, the Office of Research Administration, and the faculty member concerned. It shall be the responsibility of the faculty member to secure such approvals.

4. National Emergency

In times of national emergency declared by the Congress, the University through its established procedures and channels may accept classified research grants, contracts, assignments, and agreements in the interests of national security and appropriate to the nature of the emergency and the resources of the University.

Although thus committed to a policy of discouraging classified research projects, the University maintains a Facility Security clearance to facilitate the acquisition, storage, and use of classified information where necessary and appropriate for its research activities. Several administrative officers and faculty members hold Department of Defense security clearances. Questions and requests for assistance may be addressed to the University Security Officer through the Director of KUMC's Police Department.

Business and industry grants and contracts

Policy: All industry research grants and contracts with the exception of faculty consulting contracts must be managed by the Research Institute according to the

established policies and procedures. Core research service facilities may contract for service to internal grants and external business and industry clients.

Consistent with the University goal to increase cooperation between industry and the University of Kansas Medical Center, faculty are encouraged to support the needs of the biomedical industries in the State of Kansas through collaboration, consultation, grant and contract development and by providing access, when appropriate, to selected research equipment, faculty, staff and space.

1. Individual core research service laboratories and departments should develop internal policies that are to be placed on file with the respective school Deans. The decision to carry out this service must be based on available expertise and the recognition that the project is consistent with the mission of the Medical Center. Care must be taken to distinguish the difference between a research project where faculty and staff are used as part of the research project and service agreements where KUMC resources are utilized in a “vendor” relationship with external agencies. Faculty are referred to the relevant sections in the Handbook for Faculty and Unclassified Staff including policies on external funding of research and sponsored programs, conflict of interest, consultation, and our patent policy.

Consistent with the internal guidelines of the research laboratory, routine fee-for-services should be covered by a letter describing the service request. This letter must be submitted to the lab director. In cases where industry personnel will be using the KUMC equipment or facilities, a letter of agreement must be signed by both parties, including the KUMC authorized institutional representative. The lab director is responsible for reporting these to his/her administrator for approval to proceed with the service.

Policy: In order that KUMC, using state subsidy, not be perceived as an unfair competitor with the business community, each unit research core faculty Director or faculty member at KUMC must develop fees to users in the private sector that are comparable to fees charged by a business competitor in the region who provides the same service.

2. The recommended fee structure for KUMC core facilities, lab services, animal care facility, etc. should add an additional cost factor to cover the KUMC subsidization, which is inherent in all such facilities. A recommended additional factor is actual costs plus 50%. All these fees may be retained in the Restricted Fee account of the service facility.
3. Individual faculty members who wish to share their equipment with industry must receive permission from the responsible institutional official (Department Chair, Center Director, Dean) before proceeding.
4. When core research resource laboratories or shared instrumentation laboratories are utilized by outside business or industry agencies which are not research

agreements, the director of the laboratory (with concurrence of designated administrator) is responsible for accepting a project from the private sector. Such acceptance must be consistent with established policies that are developed by each unit and institution. The director is responsible for reporting both income to and usage of the facility on an annual basis to the appropriate administrator.

5. Laboratory Animal Resource (LAR): Service agreements, which include the animal care facility, require permission of the Director of LAR before proceeding through the routine animal care review process including review by the Institutional Animal Care and Use Committee (IAAUC).
6. In cases where KUMC agrees to provide assistance requiring a fee-for-service, the institution would not be expected to have an interest in any patents or inventions resulting from that service. However, when the service is part of a research collaborative study, consultation, grant or contract, the possibility of an interest by KUMC in patents, inventions and copyrights exists and must be disclosed to the Division of Technology Transfer and Intellectual Property in accordance with the Research Institute's policy for external funding of research and sponsored programs, patent and copyright procedures.
7. In cases where industry is provided space for research, including the placing of equipment on KUMC premises, a contract must be approved by the Vice Chancellor for Research Administration according to institutional procedures.
8. All contracts and letters of agreement requiring signatures by institutional representative(s) must be processed through the Research Institute as specified in this Handbook [*see this Section*]

Research Records Retention Policy

10/04/04

Policy

Research Records are to be retained by the University of Kansas Medical Center (KUMC) for a period of six (6) years after the submission of the final report and close-out procedures on the research project for which the Research Records were prepared, unless a longer retention period is specified by the sponsor, funding source, or regulation.

The retention of the original Research Records shall be the responsibility of the Principal Investigator on behalf of the KUMC, but at all times shall remain the property of the KUMC, unless otherwise specified by law, regulation or agreement.

Background

This KUMC policy assures that Research Records are appropriately archived and retained, and available for review under the appropriate circumstances. The Principal Investigator is responsible for the maintenance and retention of Research Records in accordance with this policy and this policy exists so the KUMC and Principal Investigator can 1) verify compliance with Federal, State, and local laws, supporting regulations, 2) to ensure the protection of intellectual property, 3) fulfill contractual obligations and sponsored project agreement requirements, 4) assure scientific integrity, 5) protect human and animal subjects, 6) assure appropriate use of recombinant DNA, etiologic agents, radioactive materials, etc., and 7) avoid disputes among researchers and protect the rights of all those participating in the research, including postdoctoral fellows, students, and staff.

Definitions

Principal Investigator or PI: The investigator, scientist, or scholar with primary responsibility for the overall design and conduct of the research, and retaining or ensuring retention of Research Records and providing access to it. The design responsibility is with person or sponsor that created and/or sponsored the research. Also referred to as the Project Director.

Research: Including, but not limited to, investigational studies of drugs or devices, laboratory studies, student research, behavioral, and outcomes research.

Research Records: Information recorded for the purpose of a research study, regardless of form or the media on which it may be recorded. Research Records may include technical data, computer software, laboratory worksheets, memoranda, notes or exact copies thereof that are the result of original observation and activities of a study, and any records that are necessary for the reconstruction and evaluation of reported results of the research and the events and processes leading to those results. Items which constitute research data under this policy include, but are not limited to: laboratory notebooks, samples of chemicals and materials synthesized during research, field specimens, voucher specimens, computer files or other electronic data, video tapes and audio tapes.

Sponsor: In clinical studies (human), a sponsor is a person or entity that initiates a clinical investigation of a study, including a drug or device manufacturer or the institution that developed the study and assumes the responsibility for compliance with applicable laws and regulations. The Sponsor does not actually conduct the investigation. A clinical investigator may serve as a sponsor-investigator. The sponsor assumes the responsibility for the study.

Procedures

Retention of Research Records

- The Principal Investigator is responsible for the collection, management, storage and retention of Research Records.

- Principal Investigators should adopt an organized system of data collection and record retention and ensure compliance by all under his/her direction regarding such data, including the use and retention of Laboratory Notebooks as appropriate.
- Research Records will be maintained in the department or division in which they were produced.
- Research records must be retained on the University campus or campus affiliate (including University approved long term storage facilities), unless specific permission to do so has otherwise been given by the Vice Chancellor for Research Administration.
- Principal Investigators must retain or otherwise archive Research Records for a minimum period of 6 years on research not involving human subjects and a minimum of 15 years on research involving human subjects or human subjects materials. If, however, the research is funded by contract, the term of the Contract/Agreement shall supersede this policy.
- If the research involved protected health information (PHI), the Principal Investigator must retain the permission to use the PHI for 6 years beyond the expiration date of the authorization (i.e. the consent form or authorization).
- Principal Investigator will maintain all documents involved in the study at the investigative site or appropriate KUMC approved storage facility.
- If the Research involves pediatric subjects or is in vitro, then the records shall be retained for a minimum of 25 years after completion or termination of the study.
- When the Research Records have met the applicable retention guideline, shred the documents and document the following: Principal Investigator name; Protocol identifiers such as Funding source or sponsor (when applicable), protocol number (when applicable), HSC, IACUC or Committee identifier; Date shredded ;Person shredding the documents and a Summary of documents shredded.
- If the study is an industry-sponsored study, prior to shredding documents or disposal of materials contact the sponsor and obtain written permission.
- When research results in an invention assigned to the KU Medical Center, and made available for commercialization, the original research lab log book which verifies the original discovery must be forwarded to the Research Institute and will be archived in a fireproof locked safe for security purposes. This archive becomes the responsibility of the Vice Chancellor for Research Administration.

Transfer of Research Records

- The Principal Investigator directing a research project may take copies of Research Records not involving human subjects, upon written approval of the Vice Chancellor for Research Administration.
- The Institution must retain all original Research Records and data. Any patient/subject records will require appropriate patient/subject authorization for use and disclosure to another entity.
- If a Grant is being transferred to another Institution with the Principal Investigator, then the Principal Investigator is responsible for leaving a complete copy of all Research Records and data with the KUMC.
- Before transferring the original Research Records, the Principal Investigator must ensure that any special conditions stated in the grant, contract, or cooperative agreement are met.
- The Department is responsible for archive of the Research Records for a period not less than six (6) years following the transfer of the Principal Investigator or the term of the grant or agreement, whichever, is longer.
- Prior to the removal of any tangible research product from KUMC, the recipient/institution must execute a material transfer agreement (MTA) with KUMC.

Access to Research Records

- Where necessary, the KUMC has the right to access all Research Records and to take custody thereof, in a manner specified by the Executive Vice Chancellor, or his/her designee.
- The Research Records shall be available to representatives of external sponsors of the research or designated governmental officials, when such access is appropriate.
- Any disputes regarding requests for original Research Records, copies, or transfer of Research Records will be resolved by the Executive Vice Chancellor or his/her designee.

Applicability

This policy shall apply to all University of Kansas Medical Center faculty, staff, postdoctoral fellows, students, trainees, and any other persons at KUMC or KUMC Research Institute involved in the design, conduct, or reporting of research at the KUMC, including all research projects on which those individuals work, regardless of funding source for the project.

Exemptions

None

Related Policies

- Faculty Handbook
- Humans Subjects Committee Policy and Procedure Manual
- KUMC Record and Retention Schedule, <http://www2.kumc.edu/finance/recordretention/>
- KUMC Policies and Procedures, <http://www.kumc.edu/guides/policyguide.html>
- 21 CFR §312.62 – Investigator Record Keeping and Record Retention for Clinical Drug or Biological Trials
- 21 CFR §812.140 – Investigator Record Keeping and Record Retention for Device Trials
- ICH Good Clinical Practice Guidelines – Part 4.9 Records and Reports
- OMB Circular A-110, §.53 [Retention and access requirements for records.](http://www.whitehouse.gov/omb/circulars/a110/a110.html)
<http://www.whitehouse.gov/omb/circulars/a110/a110.html>
- Federal Acquisition Regulation (FAR) <http://www.arnet.gov/far/>
- 48 CFR Part 27 (For contracts awarded by the Federal government) §27.403 Data rights—general 52.227-14 Rights in Data – General (Clauses & Forms)
- Kansas Statutes Annotated §75-3504, on public records disposition Agreement Term + 5 years
- National Institutes of Health (NIH) Office of Extramural Research, <http://grants1.nih.gov/grants/oer.htm>
- Statement on Sharing Data Policy (Notice # NOT-OD-03-032; Released February 26, 2003) http://grants1.nih.gov/grants/policy/data_sharing/index.htm
- NIH Grants Policy, Part II Subpart A, Availability of Research Results: Publications, Intellectual Property Rights, and Sharing Biomedical Research Resources, http://grants.nih.gov/grants/policy/nihgps_2001/part_ii_a_6.htm
- Public Health Service Policy Relating to Distribution of Unique Research Resources Produced with PHS. <http://grants.nih.gov/grants/guide/notice-files/not96-184.html>
- Sharing Biomedical Research Resources: Principles and Guidelines for Recipients of NIH Research Grants and Contracts. , <http://www.nih.gov/science/models/sharing.html>
- National Science Foundation (NSF) Grant Policy Manual (NSF 02151) §734. Dissemination and Sharing of Research Results http://www.nsf.gov/pubs/2002/nsf02151/gpm02_151.pdf

Contacts

Vice Chancellor for Research Administration: 913-588-1261

This policy shall not be construed to authorize or condone destruction of any document in contemplation of or in anticipation of, or during, any litigation or investigation. This prohibition of destruction is applicable regardless of whether the document is otherwise eligible for or past the point at which it may be destroyed. Questions regarding this requirement should be directed to the Office of the General Counsel.

UNIVERSITY OF KANSAS MEDICAL CENTER RESEARCH INSTITUTE, INC.
POLICY
Sponsored program expenditures within of the designated award dates
October 2004

Policy: Sponsored program grant and contract expenditures cannot be processed against a grant or contract prior to or after the official grant award dates.

Discussion

This policy addresses the timing and recognition of grant and contract expenditures in relation to the start and end award dates. The Faculty and Leaders Handbook states that the Research Institute “is not in a position to finance or make arrangements to finance awards for which funding is not secured in advance” [[refer back to Page 8](#)]. The PI may not make expenditures before or after the dates of the award. This applies to all purchases and payroll charges.

Exceptions to this policy may be initiated through the Vice Chancellor for Research Administration according to the procedure below (Item 2). Decisions are made on a case-by-case basis relating to funding agency policies regarding pre-award or post award expenditures, need, assurance or renewal of award, etc.

Complete grant accounting requirements can be found at the Division of Sponsored Programs Administration Web page. [<http://www2.kumc.edu/researchinstitute/spa>]

Procedures

1. Normal Approval for establishing award accounts

Grant awards and finalized contract notifications are normally issued before the actual start date of the award. Accounts are then established and expenditures can be made on the first day of the award.

2. Exception for pre award expenditures

Sometimes the faculty member has early sponsor correspondence that the award will be made and a specific date is included, but the actual award document will not arrive until after the start date of the grant. In this situation, the Research Institute may establish an account before the receipt of the actual award letter if written assurance is received from the Dean and the Chair of the Department that the Department will be responsible for the expenditures in the event that the award is not officially received. (see attached FORM MEMORANDUM) This approval will be given primarily so that the PI can receive an account number to begin the process of personnel changes and required minimal expenditures to start the project.

3. Payroll over expenditures

Any payroll over-expenditures, which are not corrected by the end date of the grant, will automatically be transferred to the Research and Development (R&D) account of the PI. If the R&D account balance is inadequate or non-existent, the transfer will be made to the Department and then to the School of the PI R&D accounts in that order. The administrator responsible for that account will be notified when this expense transfer is made. Any retroactive pay adjustments will need to be reconciled by the PI through those R&D accounts not the grant account. A 10 (ten) working day grace period following the grant end date will be honored for transferring grant employees off the grant if the PI and/or Department notify the RI that they are working on a transfer.

4. Inadequate funding within the grant period

If the PI overspends the budget of a grant between the start and end dates, it is the responsibility of the PI to transfer those expenditures to another account. Purchases will automatically be rejected and expenses will be transferred to the approved accounts. If the PI does not initiate this procedure, over expenditures will be transferred to the R&D account of the PI, Department, or School. The administrator responsible for that account will be notified when this expense transfer is made. Any retroactive pay adjustments will need to be reconciled by the PI through those R&D accounts not the grant account.

5. Post award date expenditures

The Research Institute will not honor expenditures, which are dated after the final date of the award. This includes over-expenditures of the salary budget as well as other internal and external bills.

- The PI is responsible to work within the dates of the grant award.
- The PI will be responsible to keep the remaining expenditures within the budget and remove the staff through the normal payroll transfer process of the KUMC.
- The Research Institute will notify the PI by e-mail of the approaching end date of the grant 60 days before the closing date of the grant. Failure to respond or failure to receive the notification will not be grounds to alter this policy.

6. Internal and external billing expenses

Since most funding agencies require final financial reports 90 days after the award end date, all internal and external billing will need to be submitted no later than 60 days from the award end date. Any bill whether internal or external which has been approved prior to the end date and sent to the RI within that sixty day period will be honored and charged to the grant. All other bills, which are not received within that 60-day period, will not be honored. It will be the responsibility of the PI and the Department to pay those late billed expenditures by other means.

Related Policies

OMB Circular A110 Subpart C.25(e)(1)

[<http://www2.kumc.edu/researchinstitute/spa/acct.procs.html>]

MEMORANDUM

Date _____

To: Vice Chancellor for Research Administration

From:

RE: Requested Pre Approval for Funding Grant Expenses

Since we have been notified by the _____ funding source that our proposal entitled _____ will be funded effective ____/____/____, I request approval to establish a grant account with authority to begin the minimal expenditures to start the project prior to that date. I have discussed this possibility with _____ an authorized representative from the _____ funding source and they assure us that this procedure falls within their approved regulations if approved by the Research Institute.

By the signature of my Department Chair and Dean (below) we assure the Research Institute that in the unlikely event that the grant is not funded the Department of _____ will pay any and all expenses incurred as a result of this account.

Signed:

PI _____ Date _____

Department Chair _____ Date _____

Dean _____ Date _____

UNIVERSITY OF KANSAS MEDICAL CENTER RESEARCH INSTITUTE, INC.
POLICY AND PROCEDURES FOR COST SHARING
01/05

Introduction

When the sponsor accepts cost sharing or matching, it becomes a commitment of the University. Only designated school and department level administrators are authorized to commit University funds. The PI is responsible for securing all necessary cost sharing and matching funds approvals from their academic units and school (as appropriate) in accordance with federal statutory requirements and specific agency program requirements.

This policy clarifies and strengthens the KUMC requirements and cost sharing procedures for monitoring project-by-project cost sharing and reporting.

Policy

The Research Institute must ensure that cost sharing requirements of sponsored grants and contracts agreements are proposed, accounted for and reported in a manner consistent with the requirements set forth in federal regulations, primarily the OMB Circulars A-110 (Subpart C, section 23) and A-21 (section J.13.a.). It is the responsibility of the PI and Department to assure that correct cost sharing has been identified.

Cost sharing mandated by the sponsor on Federal, State or private awards should be provided from department or school resources. Cost sharing should be limited to only what is required by the sponsor. If the sponsor does not require cost sharing or if cost sharing is not necessary to ensure the competitiveness of a proposal, PI's and departments should refrain from making such commitments voluntarily. Research Institute policy requires that Sponsored Programs Administration review agency program guidelines and policy requirements to determine whether cost sharing is necessary. Non-sponsor funded research by any PI or other personnel on a grant is considered cost sharing. All cost sharing commitments on sponsored grants must be reviewed and approved by the Department Chair, School Dean and Vice Chancellor for Administration.

Definitions

Cost sharing or matching means that portion of project or program costs not borne by the sponsor. These costs represent the commitment of the University to assure that non-sponsor resources are contributed to a project. The University's share may be in cash, in-kind or both.

Cash Contributions are recipient's cash outlay from internal or external sources can be identified in the University's accounting system. Cash contributions include:

- Salary & Benefits of University employees
- University purchased equipment
- Other expenses
- F&A costs on the above

In-Kind Contributions are value of non-cash contributions provided by non-federal third parties. In-kind contributions include:

- Volunteer services
- Donations of equipment

Criteria for Cost Sharing

To be acceptable to be used as cost sharing, expenditure(s) must meet the following criteria: (OMB A110, __.23)

- Be verifiable from official University accounting records;
- Not be used as cost sharing for any other sponsored program;
- Be necessary and reasonable for proper and efficient accomplishment of project objectives;
- Be allowable under the applicable cost principles, OMB Circular A-21;
- Not paid by federal funds from another agreement
- Be incurred during the effective dates of the grant or contract.

Cost sharing after the grant award

The PI may not change cost sharing items after a grant has been awarded if it has not been approved by the Chair and Dean in the original proposal. That is, if a PI is awarded grant dollars for specific items in the proposal, those grant dollars may not be substituted with other institutional non-grant funds after the award. This is particularly important on salary line items. If the sponsor funds a particular percent of effort, the PI must utilize those grant funds for the salary unless a budget change is approved.

The PI and the department administrative personnel must maintain sufficient documentation to substantiate the actual cost sharing contribution and make those records available to Sponsored Programs Administration and the auditors (upon requests).

Related Policies

Time/Effort

IBS

OMB issued a policy directive against coercion by agencies in June 2003, stating federal-wide policy on financial assistance program announcements (June 23, 2003 Federal Register, pages 37369-37370). Eligibility Information – Cost Sharing or Matching page 37377; Application Review Information- Criteria, page 37378.

- At least semi annually, a notice will be sent by the Research Institute to all grant personnel listed on the KUMC payroll denoting a record of the proposed time/effort percentages which have initially been designated by the employee in the grant awards and letters of appointment.
- No employee may designate more than 100% effort. Most employees should leave a percent of effort for committee or other Departmental assignments. Careful allocation, confirmed by the grant award(s) and semi annual confirmation reporting by the employee assures appropriate compliance.
- The employee or a Department designate agent who is knowledgeable about the employee effort may provide assurance of accuracy and reliability of responses.
- Employees who fail to comply with this policy will be provided with a reminder. If they do not respond, they may be subject to freezing of sponsored research accounts and/or other disciplinary action.

Related Policies

(IBS) link, (Cost Sharing) link, (Research Institute general) link, OMB Circular 121 J.8.b.