

MEDICAL COLLEGE OF OHIO

Subject: GRANTS, CONTRACTS, CLINICAL TRIALS AND ALL
OTHER SPONSORED PROGRAMS

Policy No.: 03-001

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Research and other Scholarly Activities are essential components of academic careers. MCO fully endorses faculty efforts in these activities and strives to maintain an environment supportive of Scholarly Activities. For activities using MCO (college or hospital) resources, services, or personnel, institutional policies must be followed, regardless of the source of support. However, when activities are sponsored, i.e., funded, by an external agency or corporation via a grant or contract, additional requirements must be met, since MCO, not the Principal Investigator/Program Director (PI/PD), is the grantee or contractor. As the grantee/contractor MCO has legal obligations to the grantor or contracting entity. All proposals for such extramural funds must be reviewed and approved by MCO Research & Grants Administration (RGA) PRIOR to submission, and any awards made as a result of these proposals must be set up in MCO restricted, Sponsored Program accounts monitored by RGA. These additional requirements apply to all externally sponsored programs (including non-research programs) for which there is a written application, agreement or contract with the sponsor which binds MCO to terms and conditions set forth by the sponsor, and for which any one of the following is :

- 1) The agreement obligates the (PI/PD) to a line of scholarly or scientific activity that follows a plan or workscope set forth in the proposal, protocol, or agreement, provides for systematic evaluation, or seeks to meet stated performance goals
- 2) There is a requirement for MCO to provide technical or programmatic reports;
- 3) There is a requirement for MCO to provide financial accountability, as evidenced by the submission of financial reports to the sponsor, an audit provision, or for return of unexpended funds;
- 4) There is a requirement that something of value be provided to the sponsor or that the sponsor is promised any rights, or option thereto, to intellectual property discovered/developed during the program
- 5) There is a requirement for an institutional commitment to maintain confidentiality of information provided by the sponsor
- 6) There is a requirement for MCO to define and/or track personnel effort devoted to the program
- 7) There is a requirement for MCO to cost-share any portion of the program costs
- 8) There is a requirement that a portion of the program be subcontracted to another entity; or

- 9) There is a requirement for assurance of regulatory compliance (e.g., IRB or IACUC approval of protocols).

The above characteristics of an extramural grant/contract to support Sponsored Programs distinguish this type of support from a GIFT. Gifts are irrevocable transfers of assets made by the donor without any expectation or receipt of economic benefit or tangible compensation (e.g., deliverables such as data, services, etc.) from the recipient commensurate with the worth of the gift. Gifts should be directed to the MCO Foundation, but support meeting the above criteria must be deposited into restricted, Sponsored Program accounts in the College, unless an exception is approved in writing in advance by the President. For additional information regarding Gifts, see MCO Policy # 01-047 (Private Sector Funding).

APPLICABILITY: All grant, contract, clinical trial and other Sponsored Program applications (collectively, “Sponsored Programs”) that have a MCO faculty/staff member or student as the PI/PD and are part of that individual’s MCO responsibilities must name MCO as the grantee/contractor, regardless of the performance site. For the purposes of this policy, a Clinical Trial is defined as a study, generally involving human subjects, designed to assess the safety and/or efficacy of drugs, devices, diagnostics, treatments, or preventive measures. All MCO personnel are encouraged to contact RGA staff early in the proposal development process so that informed decisions regarding an application can be made in a timely manner before a proposal deadline.

In cases where an MCO faculty/staff member or student has a role at another institution/organization (e.g., a MCO staff member who is a student at another educational institution, or a part-time MCO faculty member also employed by another entity), only those Sponsored Program applications that are relevant to the MCO staff/faculty member’s MCO responsibilities must name MCO as the grantee/contractor. When a Sponsored Program application is for a program that is relevant to an individual’s duties on behalf of the other institution/organization, the application may be submitted through that other institution/organization. The PI/PD may request to have MCO be the grantee organization on his/her behalf, even when MCO is not required to be the grantee. In such cases, RGA will decide, based on the merits of each case whether MCO should comply with the request. For example, if a MCO staff member is working on an advanced degree at a neighboring institution, and it would be more convenient for the staff member to have the Sponsored Program account set up at MCO, the staff member may request that MCO act as the grantee. To avoid future questions, individuals should disclose to MCO RGA any Sponsored Program applications that will be submitted through other organizations. One important reason for this disclosure is that decisions must be made regarding the applicability of the MCO regulatory compliance assurances to the activity, even though MCO may not be the grantee/contractor of record.

INSTITUTIONAL APPROVAL: Grants or agreements for research (including clinical trials) or other programs involving MCO faculty cannot be entered into between individual faculty members and a sponsoring agency or corporation. These agreements must be made between MCO and the sponsoring agency or company. Only a salaried MCO faculty member or other qualified MCO salaried contract employee may serve as MCO’s PI/PD on Sponsored Program agreements. The PI/PD must be in a position to provide direct, personal, day-to-day oversight of activities and personnel associated with the Sponsored Program. Students or postdoctoral fellows may be the PI/PD on Fellowship grants when sponsored by a salaried MCO faculty member. Any exceptions to the above criteria regarding the eligibility of an individual to serve as the PI/PD of a Sponsored Program must be approved by the Associate Vice President for Research. Because of the obligations MCO assumes as the grantee/contractor, protocols and budgets for ALL applications for grants, agreements or contracts must be reviewed and approved by RGA and signed by one of the MCO officials authorized by the Board of Trustees to commit MCO to externally sponsored agreements (MCO Policy #03-009). To facilitate this review the PI/PD and other personnel named in grant or contract proposals or research agreements must disclose to RGA any and all consulting or other arrangements they may have with the potential sponsor and provide to RGA copies of all written agreements relating to these arrangements. This disclosure is necessary to ensure that terms of personal consulting and other agreements (e.g., confidentiality or intellectual property commitments) do not conflict with the terms of the grant or contract agreement between MCO and the sponsor. Research & Grants Administration

review must be completed prior to transmission of any application/request to potential extramural sponsors. This institutional approval is required by MCO even if it is not a requirement of the sponsor. RGA will obtain this approval/signature after review of the proposal, budget, agreement, etc. Normally, the Associate Vice President for Research provides MCO approval and signs these documents.

A copy of the MCO Proposal Review and Approval Form, aka the "Blue Sheet", (which may be obtained from RGA) must accompany applications submitted to RGA for review. This must be completed and signed by the PI/PD and his or her department chairperson, or the appropriate Dean when the PI/PD is a Department Chair. All collaborators and their Department Chairs must also sign this form. In addition, if Hospital services are to be utilized, the budgeted costs of those services must be approved by Hospital Administration. In many cases RGA review cannot begin without the information (e.g., required regulatory protocol numbers, etc.) contained on this form. Stamped or "per" signatures are not acceptable on this form because of the commitments and certifications that it imposes on individuals, departments and schools.

In order to ensure adequate time for RGA review of all components of a grant/contract proposal prior to its submission, it is necessary that the COMPLETE PROPOSAL be submitted to RGA no less than 5 full working days prior to the agency deadline. [NOTE: Although this 5-day review period has not been strictly enforced to date, this may become necessary in the near future.]

[NOTE: In the case of sponsor-initiated research or clinical trial agreements, it is essential that all items associated with a Sponsored Program, including supporting regulatory compliance protocols, be delivered to RGA as soon as the PI/PD receives them from a sponsor. RGA cannot be responsible for delays caused by late initiation of the review/approval process on the part of the PI/PD]

ELECTRONIC SUBMISSION OF PROPOSALS: Proposals submitted electronically are subject to the same MCO review and approval requirements set forth above. The PI/PD may prepare proposals using electronic forms, including those on agency websites, but final submission of the proposal and any associated institutional representations and certifications must not occur prior to final approval by RGA. It is the responsibility of the PI/PD to provide RGA a paper copy of the electronically submitted proposal, exactly as submitted to the agency.

Because of the number of applications that RGA may have to deal with for a particular agency deadline, and because no one can predict what malfunctions (e.g., MCO computer systems and network, MCO internet access, agency website and computer systems, etc.) may occur at or about the time of the deadline, grant applications that must be submitted electronically must be delivered to RGA in a "ready to submit," final form, i.e., already approved by RGA, at least 48 hours prior to the published agency deadline to guarantee delivery to the agency by the deadline. Although some granting agencies have set their receipt deadline for electronic filing at MIDNIGHT on the receipt date, RGA will NOT be able to extend its workday beyond 5PM on deadline dates to accommodate investigators who have waited until the last minute to finalize their applications.

FUNDING FOR POTENTIALLY CONTROVERSIAL PROGRAMS OR FROM POTENTIALLY

CONTROVERSIAL SOURCES: In considering whether to seek or accept funding from sources (e.g., tobacco companies or firearms companies) or for programs: (e.g., weapons research) which might prove controversial or inappropriate, MCO will consider a number of factors, including the following: 1) Any negative effect on academic freedom of MCO faculty, students or employees; 2) The connection between the purpose of the funding and the nature of the source; 3) The balance between any potential societal benefit of the purpose of the funding and any societal harm which may be advanced by identification of MCO with the sponsor; 4) The potential benefit to the MCO community of the purpose of the funding versus the potential effect of receipt on the reputation of MCO; 5) The appearance of an organization's use of the MCO campus or the name of MCO to promote a commercial purpose; 6) The potential effect on MCO's future recruitment of faculty or students or on MCO's or MCO Foundation's future fundraising; 7) Whether sponsor has a history of having committed criminal conduct or fraud; 8) Accepted national and community practices with respect to applying for and accepting

funding from the proposed source for the same or similar purposes; and 9) Any issues of safety, order and discipline within the MCO community that might result from association with the proposed sponsor.

Questions regarding whether a particular program or funding source may be controversial should be referred to the Associate Vice President for Research for communication to the President who, after consultation with appropriate individuals and groups, shall make a determination regarding whether MCO shall participate in such programs, or accept funding from such sponsors.

Based upon the above considerations a determination has been made that MCO will not accept Sponsored Program funding from tobacco companies.

RESPONSIBLE CONDUCT OF RESEARCH AND OTHER SCHOLARLY ACTIVITIES: It is essential that every PI/PD be familiar with the tenets of MCO Policy # 03-012 entitled "Responsible Conduct of Research and Other Scholarly Activities" and instruct his or her employees and students in the principles found in this policy. Furthermore, it is important that each PI/PD insist that all program-related activities be conducted in compliance with the principles of this policy.

RESPONSIBILITIES OF THE PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR: The PI/PD on a grant awarded to MCO must have a thorough understanding of the policies of the sponsoring agency and MCO to ensure that his/her program is conducted in compliance with those policies. Although RGA assists in ensuring programmatic compliance, primarily by monitoring expenditures for restricted, Sponsored Program accounts, as the individual closest to the work, the PI/PD is ultimately responsible for all program activities. In requesting institutional endorsement of a grant/contract proposal, the PI/PD represents that he or she agrees to be bound by the policies of both the sponsor and MCO, as well as all laws and regulations governing program activities. The PI/PD is responsible for informing all study personnel that he or she assigns to the program of their responsibilities to both the sponsor and MCO and providing personnel training in techniques and procedures associated with protocols to be employed. Finally, the PI/PD is responsible for ensuring that all study personnel understand and comply with all federal regulations affecting the program(s) on which they work (e.g., human and animal subject regulations).

If the research involves human or animal subjects, or biohazardous materials it is the responsibility of the PI/PD to ensure that MCO Institutional Review Board (IRB), Institutional Animal Care and Use Committee (IACUC), or Institutional BioSafety Committee (IBC) approval is obtained prior to initiation of the research, initiation of any protocol modifications, or addition of personnel. In addition, the PI/PD must ensure that required regulatory protocol(s) are renewed in a timely manner. A lapse in approval of a required regulatory protocol potentially could result in loss of grant/contract funding. It is also the responsibility of the PI/PD to know the federal regulations and MCO policies governing use of humans and/or animals in research. Lack of understanding of these regulations and policies cannot be used as an explanation for non-compliance. The PI/PD must ensure that all members of the research group have received appropriate training for their activities and that this training has been documented appropriately in the MCO IRB, IACUC, or IBC office. It is also the responsibility of the PI/PD to obtain written approval of the IRB, IACUC, or IBC for all study personnel prior their beginning working on a program/project. In short, the PI/PD must assume the responsibility for the actions of those working under him or her.

Agency-Specific PI/PD Responsibilities

If your grant is from NIH, the NIH Grants Policy Statement, which is referenced in the Terms of Award of each NIH grant, is the "rule book" that must be followed, in addition to any other Special Terms & Conditions contained in your specific Notice of Grant Award (NGA). You received a copy of your NGA via e-mail from RGA at the time MCO received the award. A copy of the *NIH Grants Policy Statement* is always available via the world wide web at < http://grants1.nih.gov/grants/policy/nihgps_2001/index.htm>.

If your grant is from another HHS/PHS agency, such as HRSA, the policies governing your grant, *the PHS Grants Policy Statement*, is referenced in the Terms of Award contained in your Notice of Grant Award, as the "rule book" that must be followed, in addition to any other Special Terms & Conditions contained in your specific NGA. A copy of the PHS Grants Policy Statement is always available at <http://grants.nih.gov/grants/policy/gps/>.

If your grant is from the National Science Foundation, the regulations that you must follow are defined in the NSF Grants Policy Manual. A copy of this document is always available at <http://www.nsf.gov/pubsys/ods/getpub.cfm?nsf02151>.

If you have a Federal CONTRACT, the regulations that you must follow are defined in the Federal Acquisition Regulations (FAR) clauses that are referenced in your specific contract. A copy of the full text of the Federal Acquisition Regulations is always available at <http://www.arnet.gov/far/>.

FACILITIES AND ADMINISTRATIVE COSTS (FAC): When MCO facilities and/or personnel are utilized for Sponsored Programs, the sponsoring agency or corporation must reimburse MCO for the FAC (formerly known as Indirect Costs) associated with the Sponsored Program. FAC includes those institutional costs which cannot be identified with a specific Sponsored Program (e.g., library operation, facilities and infrastructure support and administrative costs). Call RGA for MCO's current Federal FAC rate. Any reduction from this rate for a particular program sponsored by a non-Federal entity requires MCO to cost-share the difference between the Federal FAC rate and the rate allowed by that particular sponsor. All deviations from the Federal FAC rate must be approved in advance by the Associate Vice President for Research. Individual investigators do not have the authority to negotiate the FAC rate for their Sponsored Program(s), and in some cases, doing so could represent a conflict-of-interest in violation of Ohio law. The practice of allowing the program sponsor or any other third party to purchase supplies, etc., directly for use by MCO investigators, thereby circumventing the MCO FAC charges and MCO purchasing/receiving policies and procedures, or making direct payments to study personnel or study subjects, is strictly prohibited. All such transactions must "flow" through the MCO restricted, Sponsored Program account set up for support of the specific Sponsored Program.

To avoid an inadequate "bottom line" being established prematurely for a Sponsored Program, even preliminary budgets should be discussed with RGA prior to contacting a potential sponsor to ensure that an adequate budget, including FAC, has been projected. When the basis for FAC is anything other than Total Direct Costs, FAC is budgeted for convenience based on the PI/PD's Direct Cost budget, but actual FAC recovery is determined by expenditures and, if necessary, monies may be rebudgeted from Direct Costs to FAC. For example, if the basis for FAC is Modified Total Direct Cost (MTDC), as is the case for all MCO federal grants/contracts, equipment and patient care expenses are excluded from FAC. If the budget for a particular grant/contract is established with all of the funds in one of those two FAC-excluded categories, no monies will be budgeted for FAC, but if any monies are re-budgeted and expended for personnel, supplies or any other FAC-applicable category, monies must also be re-budgeted from Direct Cost categories to pay the applicable FAC. In short, FAC is not capped at the budgeted amount, but will be collected on all FAC-applicable expenditures, even if rebudgeting from Direct Cost is required. When clinical trial budgets are quoted by the sponsor as a specified dollar amount per patient or for the entire study, this dollar amount represents Total Cost, which includes the MCO FAC. Revenue from such clinical trials will be divided in the MCO restricted, Sponsored Program account between Direct Cost and FAC based on the applicable FAC rate for that study.

MANAGEMENT OF FUNDS: All funds obtained from grants, agreements or contracts to which this policy applies must be deposited in an MCO restricted, Sponsored Program account (in the 93xxxxxx, 94xxxxxx or 95xxxxxx series) monitored by RGA, and used only for allowable expenses associated with the specific Sponsored Program. MCO's tax-exempt Foundation cannot be utilized for funds associated with Sponsored Program grants, agreements or contracts. Administration of grant, agreement or contract funds must be in accordance with the policies of: 1) the Medical College of Ohio, 2) the State of Ohio, and 3) the sponsor. When the sponsor does not

have policies governing a specific issue, policies of the National Institutes of Health (as defined in the most recent edition of the [NIH Grants Policy Statement](#)) must be followed. NIH policy allows flexibility, yet provides a consistent policy applicable to virtually every type of expenditure. A copy of the [NIH Grants Policy Statement](#) is available via the RGA web site. Departmental copies will be provided upon request. Signature of the PI/PD or other authorized signor on purchase requisitions, personnel action forms or other expenditure requests represents that the requested expenditure is for items or services necessary for the conduct of the program supported by the grant/contract account on which the request is being made. Any expenditures not fully justifiable as program-related may be interpreted by the IRS as unrelated business income to MCO, which is taxable, and therefore are not allowable. Prior to the termination date of a grant, if a grant account runs out of money, the salary source for non-faculty personnel charged to that grant must be changed to another account. If the appropriate paperwork is not received by MCO Payroll, prior to processing paychecks for the first pay period after the grant terminates or runs out of money, all non-faculty personnel retained as employees will be charged automatically to the Sponsored Programs incentive account of the PI/PD, if one exists, or the Sponsored Programs incentive account of the department of the PI/PD primary academic appointment, if necessary. Salary source changes must also be processed for faculty and other contract employees at the same times described above, but these source changes require considerably more lead time (6-8 weeks). In the event a grant/contract account becomes overexpended, the PI/PD must correct the overexpenditure promptly by authorizing the transfer of allowable expenses to some other, non-restricted, account (see Cost Transfers section below). In cases where this is not done, expenses will be transferred automatically to the PI/PD's Sponsored Programs incentive account, or in the absence of such an account, to the Sponsored Programs incentive account of the department of the PI/PD's primary academic appointment.

Internal MCO budgets provided by the PI/PD for fixed-price research contracts (including clinical trials) must agree with the detailed budget or budget worksheet(s), if any, provided by the sponsor. All sponsor-provided budget material must be provided to RGA along with the sponsor's proposed research agreement. In the absence of a sponsor-provided budget, the internal MCO budget must add up to the total direct cost of the contract less Professional time and effort of MCO faculty investigators (See Faculty/Staff Compensation section below). Any anticipated "residual funds" should not exceed 10% of the total direct cost

COST TRANSFERS, OVERRUNS, AND ACCELERATED AND DELAYED EXPENDITURES

Cost transfers between grant/contract accounts that represent corrections of clerical or bookkeeping errors should be accomplished within 90 days of when the error is discovered. The transfers must be supported by documentation that fully explains how the error occurred and a certification of the correctness of the new charge by the PI/PD, MCO official, or consortium participant, as applicable. An explanation merely stating that the transfer was made "to correct error" or "to transfer to correct Program" is not sufficient.

STUDY PERSONNEL: Contractual obligations contained in research agreements and policies of nearly all sponsoring agencies require that all personnel working on a study be employees or students of the Medical College of Ohio. In addition, MCO Liability Control requires that all individuals working on MCO-related Sponsored Programs be one of the following: 1) paid MCO faculty; 2) volunteer MCO faculty; 3) MCO employee; 4) registered MCO student; or 5) registered MCO volunteer. If you anticipate the need to utilize non-MCO personnel, including individuals employed by APMCO, these individuals must be registered as MCO volunteers through the MCO volunteer office and cannot be paid for their Sponsored Program-related activities. Any study personnel who are to be paid for Sponsored Program-related activities must be MCO employees or registered MCO students. All investigators involved in MCO clinical trials must have a regular or volunteer faculty appointment at MCO. When MCO employees, whose primary MCO job is unrelated to a given Sponsored Program, work on that program on a part-time basis, it is the responsibility of the PI/PD of the Sponsored Program restricted account paying for the part-time work and the employee to guarantee that the

hours being paid from the Sponsored Program restricted account do NOT overlap with the employees' primary MCO job. All such arrangements must be in compliance with MCO policies regarding employment issues. All Co-investigators on a grant/contract proposal must commit to some level of effort on the project, but Consultants do not have to commit to any level of effort.

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

REGULATORY COMPLIANCE: All research protocols involving human subjects must be approved by the MCO Institutional Review Board (IRB) prior to establishing an MCO account for the expenditure of funds supporting the study and prior to entering any patients into the study (See Policy #02-001). Research conducted by MCO faculty at performance sites other than MCO must also be approved by the MCO IRB (as well as the IRB of the non-MCO performance site). . If the non-MCO performance site (e.g., a nursing home) does not have an IRB, and that entity is not "engaged in research," written permission to perform the project at that facility must be obtained from an authorized representative of the facility, prior to review by the MCO IRB. This requirement must be met even when no grant/contract funds are available for support of the research program. The same requirements also apply to ALL protocols involving animal subjects, which must be approved by the MCO Institutional Animal Care and Use Committee (IACUC) (See Policy #03-007).

The PI/PD or a co-investigator on any research grant, agreement or contract requiring IRB, IACUC, or IBC approval must be the PI/PD on the IRB, IACUC, or IBC protocol(s) supporting the work described in the research grant, agreement or contract. In the case of a Fellowship application, the faculty sponsor/mentor for the trainee applicant must be the PI on the regulatory protocol(s) supporting the work described in the application, and the trainee applicant must be among the authorized personnel on the same regulatory protocol(s). Similarly, research involving hazardous chemicals must be approved by the Academic Chemical Hazards Committee (ACHC) (See Policy #03-004) and research involving recombinant DNA or biohazardous materials must be approved by the IBC (See Policy #03-006). All of these regulatory committees are coordinated by RGA, and protocol forms for each committee may be obtained from that office or via its website
<<http://www.mco.edu/research/mcoforms.html>>.

CONFIDENTIALITY: MCO does not accept grants/contracts to support classified research. The existence of a Sponsored Program agreement is to be a matter of public record. In all cases, the existence of the agreement, the name of the sponsor, the study title, inclusive dates of the study, and the dollar amount of the sponsorship may be made public by MCO. Sponsored Programs allowing MCO personnel access to and/or use of sponsor's confidential or proprietary information, data, or material will be accepted only if restrictions regarding access, use, and protection of such information, data, or material do not restrict the full dissemination of scholarly findings made under the grant or contract and do not put MCO in a position of assuming financial liability. Sponsor's confidential information, data, or material should be labeled as such by the sponsor before release to MCO project personnel. If the sponsor, or sponsor's agents disclose confidential or proprietary information verbally to MCO personnel the confidential nature of the disclosure should be communicated at the time of the disclosure and a written summary of said disclosure and a declaration of its confidential nature must be provided to the MCO PI/PD within 30 days of the disclosure.

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

- 1) in order to secure intellectual property rights pertaining to research discoveries/inventions prior to public disclosure;
- 2) in order to coordinate the publication of the results of multi-center studies in which MCO

investigators participate; and 3) in order to allow for sponsor's review of manuscript(s) prior to publication for identification of any of sponsor's confidential information which may have been included unintentionally. Agreements which define study results as confidential information not to be published or which convey to the sponsor the right to veto publication or to censure the content of publications will not be entered into.

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

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

INCENTIVES PAID BY SPONSORS: All incentive payments, either monetary or non-monetary, in excess of budgeted Sponsored Program costs paid by sponsors in association with clinical trials or other Sponsored Programs must receive prior approval by RGA and by the MCO IRB (if human research subjects are involved). Approved incentive payments may NOT be paid directly to investigators, other Sponsored Program personnel, or study subjects, but must be deposited in the same MCO Sponsored Program restricted account utilized for other monies received in support of that Sponsored Program.

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

PROTOCOL-INDUCED PATIENT-CARE COSTS: The research costs associated with clinical trials of drugs or devices conducted according to the sponsor's protocols should be fully funded by the sponsor and should not

be supported, in whole or in part, with other funds, including the health insurance of study subjects, nor should they be cost-shared by MCO. Protocol-Induced patient-care costs for study subjects, i.e., the costs of interventions, procedures, lab tests, drugs, or devices that the study subject would not have been exposed to had he/she not volunteered to participate in the research protocol, must be billed to the grant/contract restricted account associated with the investigational protocol for which study subjects have volunteered. Where research is conducted in conjunction with, or as a part of, the routine medical care of patients, the costs of Routine Patient Care (also known as Standard of Care) may be reimbursed by third party payers to the extent such costs are not budgeted in the grant account. Routine Patient Care is medically reasonable, necessary, and ordinarily furnished (absent participation in any research) in the treatment of patients by physicians, or other providers under the supervision of physicians, as indicated by the medical condition of the patients. Examples of Protocol-Induced patient care costs include, but are not limited to, costs associated with weekly lab tests for a condition usually requiring a single test, or monthly CT scans for a condition usually requiring only a single scan.

COSTS FOR TREATMENT OF PROTOCOL-INDUCED INJURY TO SUBJECTS: Company-sponsored Clinical Trials of drugs and devices using company-written protocols which require review/approval at a convened meeting of the MCO IRB will be accepted by MCO only when the sponsor assumes full responsibility for the reasonable cost of medical treatment for Protocol-Induced injuries to study subjects. Protocol-Induced Injuries are injuries directly resulting from interventions that study subjects would not have been exposed to had they not volunteered to participate in the study. It is not acceptable for a sponsor to restrict its responsibility for payment for treatment of Protocol-Induced injuries to only those injuries directly associated with the administration/use of the study drug or device, nor is it acceptable for the sponsor to limit its responsibility to immediate or emergency care for Protocol-Induced injuries. Normally, this provision will be part of the clinical trial agreement between MCO and the sponsor, but this requirement may also be met by receipt of an appropriate letter making such a commitment which is signed by an authorized representative of the sponsor. It is not acceptable for such arrangements to require billing of third party insurance companies in lieu of recovery of such costs directly from the sponsor, nor is it acceptable for such agreements to include provisions restricting participation of human subjects on the basis of medical insurance coverage status or the subject's ability to pay. [NOTE: Protocol-Induced Injuries do NOT include normal progression of the subject's disease, or conditions not directly resulting from interventions that the subjects would not have incurred had they not volunteered to participate in the study.]

This policy applies to all company-sponsored clinical trials of drugs and devices using company-written protocols which require review/approval at a convened meeting of the MCO IRB. Exemptions to this policy will be considered, on a case-by-case basis, for company-sponsored, open-label, studies which utilize pharmaceutical agents approved by the FDA for sale in the U.S. in all arms of the study, and for clinical trials that involve the use of medical devices approved by the FDA for sale in the U.S., as well as those non-experimental/investigational (Category B) devices which have been approved for Medicare payment by the Centers for Medicare and Medicaid Services (CMS).

That section of informed consent documents describing payment for protocol-induced subject injury should reflect accurately the language in the clinical trial agreement covering this subject, or other form of sponsor commitment for payment for subject injury. In the event that a study is given an exemption from this policy, the informed consent documents must state accurately how payment for treatment of protocol-induced injuries will be handled.

CONSULTANTS: In general, MCO faculty cannot serve as paid consultants on research grants, agreements or contracts awarded to MCO. When an outside agency contracts with MCO to provide research, it agrees to reimburse MCO for the costs of that work, including all personnel costs, except for any approved MCO cost-sharing. Appropriate reimbursement for all faculty effort devoted to that Sponsored Program should be included in the contract. Accordingly, it is not permissible for a sponsor to pay MCO faculty additional

compensation (e.g., as a consultant) for the performance of the same work. Nor is it permissible for the sponsor to pay a consulting fee which is, in essence, intended to compensate the faculty member for interpreting the data obtained under the contract. Data Interpretation represents an extension of the basic work and, in the event that more faculty time is required, MCO should be reimbursed for it. (Also see STUDY PERSONNEL section of this policy)

CONFLICT-OF-INTEREST: All personnel responsible for the design, conduct or reporting of research in Sponsored Programs must complete a MCO disclosure of potential conflict-of-interest (Academic Employee Disclosure of Potential Conflict-of-Interest for Sponsored Programs form) at the time of proposal submission. This disclosure document must be completed (and signed) by the only person who knows about the investigator's finances, i.e., the investigator him or herself. "Per" signatures or stamped signatures of investigators or chairs are not acceptable on this form. This form, which must be signed by each signatory's department chair (if any financial interest is disclosed), will be reviewed by RGA and the MCO Conflict-of-Interest Review Committee, if required under the terms of the MCO Conflict-of-Interest Policy (Policy # 03-005). This committee will make recommendations for reducing, managing, or eliminating any conflicts-of-interest or the appearance thereof.

GENERAL: An important role of Research & Grants Administration is to facilitate the scholarly activities of the MCO faculty in both basic and clinical sciences. Although RGA is charged with the responsibility of assuring that proposals leaving MCO and Sponsored Program dollars expended by MCO investigators comply with the policies and regulations of sponsoring agencies and the College, RGA personnel will do everything in their power to satisfy this charge without placing undue burdens on investigators.

Source: Executive Vice President and Provost

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