Minneapolis Medical Research Foundation
Sponsored Project Administration

Guidance and Procedures

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Introduction

The Minneapolis Medical Research Foundation (MMRF) was founded in 1952 and is the third largest non-profit medical research institution in the State of Minnesota. MMRF consistently ranks nationally in the top 10% of institutions receiving funding from the National Institutes of Health (NIH). MMRF occupies approximately 60,000 square feet on the Hennepin County Medical Center (HCMC) campus. This includes clinical research space, basic science laboratories, AAALAC accredited large and small animal facilities and space for research administration and accounting services.

The MMRF administers sponsored medical research taking place on the HCMC campus. Its mission is to improve patient care and the health of our community through research and education. The MMRF administers approximately $30 million in research funds annually, roughly half of which is federally funded. The organization operates under the leadership and direction of the MMRF Board of Directors, President, Vice President, Vice President of Operations, and the Secretary/Treasurer.

The MMRF is a non-profit subsidiary of the Hennepin County Medical Center. The MMRF's tax-exempt status is granted by IRS rules that define the foundation as a scientific research organization under section 501(c)(3) of the Income Tax Regulations Code. The MMRF is organized and operated for the purpose of carrying on scientific research and educational activities that serve the public interest.

The Hennepin County Medical Center (HCMC) is a public teaching hospital, and is the centerpiece of Hennepin County's Health System. It occupies more than four city blocks in downtown Minneapolis, and also operates several suburban outreach centers in the Twin Cities metropolitan area. The primary purpose of the HCMC is to provide the highest quality hospital services available to the general public, and in particular, the indigent and other under-served populations.

The MMRF Office of Grants and Contracts serves as a liaison between outside sponsoring agencies and investigators. Its responsibilities include submitting proposals, negotiating and administering awards, and interpreting and implementing sponsor and MMRF regulations. MMRF Grants and Contracts hosts workshops at regular intervals and provides material from those trainings on the website (www.mmrf.org).

This manual has been prepared as a general resource and overview for MMRF Investigators and staff. It is the responsibility of staff involved in the management of research on this campus to be aware of and comply with the organization's policies and the procedures described in this manual.

Due to the evolving nature of the regulatory requirements applicable to medical research, these policies and procedures do change from time to time. The MMRF research community will be notified of changes by regular updates and revisions to this manual via the MMRF Clinical Trials Training ListServe and the MMRF website.

Part I: Proposal submission

A Sponsored Project is a financial award from an external agency for the conduct of a specific scope of work which contains financial or other reporting requirements, or specific terms and conditions, or both. Sponsored projects generally come with an expectation from the sponsor that the work will be conducted in accordance with the submitted proposal. Sponsors can include State or Federal agencies, foundations, other non-profit organizations, or private and commercial enterprises. Sponsored projects are different from gifts (donations or contributions), in that gifts are generally given without an expectation for specific outcomes or services. Questions regarding gifts should be directed to the MMRF Controller.

Submission of a proposal to an outside agency generally requires institutional authorization, approving the contents of the proposal, and assuring the agency that it has been prepared in accordance with MMRF institutional policies. It is the Principal Investigator's (PI) responsibility to notify the Office of Grants and Contracts that a proposal is being submitted, and to provide a copy of the proposal to the Office of Grants and Contracts within a reasonable period of time prior to submission to allow for adequate review and approval, and changes if they are necessary.

The MMRF Grants Office recommends completed electronic proposal packages be submitted to our office for review and submission at least three full business days prior to the deadline. The NIH requires an error-free submission prior to 5 pm local time on the due date. Grants.gov can take up to two business days to validate and forward a proposal to the agency, and if there are delays in either process at NIH or Grants.gov, and there are problems identified with the proposal, there may not be sufficient time to correct the proposal and resubmit it prior to the deadline. The MMRF Grants Staff will always endeavor to submit a complete and correct application whenever it is received; however, for the reasons outlined above, a minimum of three business days is recommended for our office to review and submit to help ensure a successful submission.

A. Compliance Approvals

The MMRF requires a cover form, an "Application for External Support" to be completed and signed for each externally funded project and/or proposal. This form provides useful summary information regarding the project timeline and budget, and assures that certain MMRF regulatory obligations, (such as conflict of interest disclosure, research subject protection, and hazardous material use authorization) have been addressed. The "Application for External Support" is available on the MMRF Website.

It is the PI's responsibility to file protocols and obtain approvals from any required compliance committees if human subjects, animals, or hazardous materials are involved in the project. Disclosure requirements of MMRF's Conflict of Interest policy must also be observed. Compliance committee approvals are not be required at the time of proposal submission (and are therefore pending), however, they must be obtained prior to the commencement of work, and/or the expenditure of funds on any project. Some

sponsors may not accept 'pending' status on proposal submissions or may have other deadlines for obtaining compliance approvals.

B. Budgeting

The budget, or business section of a proposal, provides a sponsor with an idea of the amount and distribution of funds necessary to conduct a project. Costs that may be included in the budget vary by sponsor, but generally include salaries, fringe benefits, supplies, space rent, equipment, and indirect costs. As proposed budgets form the basis for financial awards, it is the responsibility of the PI to ensure the completeness and accuracy of proposal information. Assistance with budget and proposal development can be obtained from the Office of Grants and Contracts and the Office of Clinical Trials Training, if adequate notice is provided prior to a submission deadline.

Unless prohibited by published sponsor policy, institutional indirect costs must be included in a project budget at the rate applicable to the type of sponsor. Annual rate schedules are provided to investigators from the MMRF Chief Financial Officer on the "MMRF Rate Sheet."

C. Calculation of Indirect Costs

Overhead (or indirect costs) is an essential part of a proposal budget. Indirect costs are dollars recovered by the organization to pay for cost of the common infrastructure necessary to run the organization, such as purchasing, accounting, grant administration, and human resources, costs for compliance, (such as the committees that protect human and animal subjects) and other common costs such as facility construction and the purchase and maintenance of common equipment. At the most basic level, indirect costs cover the shared activities of the organization. The various indirect cost rates are an attempt to distribute these shared costs to the activities of the organization in an equitable way.

Indirect cost rates are applied to the following categories of MMRF activities:

Federal rates are applied to the salaries and wages of federally funded research projects based on the rate negotiated with the federal government annually.

Industry rates are applied to revenues/cash receipts received from commercial organizations under contract, and are set by MMRF Board of Directors.

Contribution rates are applied to donations from non-federal/non-commercial organizations that do not have a published indirect cost rate.

1. Overhead on Federal Projects (Salaries and Wages Base)

The Federally negotiated rate is based on **salaries and wages only**. The overhead rate that is applicable is calculated based only on the salaries and wages budgeted

in the project. "Salaries and Wages" is not the same as "Modified Total Direct Costs", which is a common base for educational institutions. For instance (30% is used here only as an example), for a project with $100,000 in budgeted salaries, an additional $30,000 (30% of the salaries and wages) should be included for institutional indirect costs (in addition to all other direct costs). The MMRF indirect cost rate structure is complex, and it is prudent to double-check your Rate Sheet to ensure you are using the most current rate applicable in your situation, and/or contact the Grants Office to confirm the correct rates to be used. A common error is to include the cost of fringe benefits in this calculation. Fringe is personnel cost, but is not a part of salaries.

2. Overhead on Non-federal Projects (Cash Receipts Base)

Non-federal projects are charged overhead based on the cash receipts deposited or project income. This means that overhead is taken at the time of payment from the sponsor, instead of at the time of expense by the project. This is an important distinction; if overhead is not calculated correctly, a project may not have enough revenue to cover all of its costs.

When calculating overhead on a cash receipts basis, determine the total direct costs necessary to complete the work proposed, then divide total direct costs by one minus the overhead rate. This will tell you the total dollars that will need to come into the organization in order to pay for the direct costs and the overhead (Direct Costs/1 - Overhead Rate = Total Costs). For example, consider an educational seminar project with a direct cost budget of $100,000. Assuming an overhead rate of 15%, the total costs of the project will be $117,647 ($100,000/.85 = $117,647).

D. When the MMRF is a Subcontractor

If the MMRF is to serve as a Subcontractor on a project, at the time of proposal submission it will usually be necessary to submit a budget and a letter of intent to the organization serving as the prime institution for the project. A letter of intent needs to be signed by an authorized institutional official; at the MMRF this person is the Chief Operating Officer. The PI is not a position that has been formally delegated the authority to legally bind the institution.

To obtain a signed Letter of Intent, provide the following information to the Office of Grants and Contracts:

1. Title of the Project
2. Name of MMRF PI
3. Name of the PI at the Prime Institution
4. A budget for the project
5. A work-scope, or short description of the work to be performed
6. Name/address of individual to whom the letter should be addressed
7. Name/address of sponsoring agency
8. Sponsor Guidelines

It is always wise to obtain subcontract guidelines from the Prime Contractor well before a proposal deadline in case MMRF is required to provide additional documentation (copies of bylaws, verification of tax-exempt status, etc.). While most standard information is on file at MMRF, some documentation (such as certificates of insurance) requires significant lead-time to obtain.

E. Departmental Administration Accounts – Bid and Proposal Costs

Bid and Proposal costs include the staff time and resources expended in pre-award preparation for a project. This includes writing technical proposals, preparing budgets and IRB applications, travel required in submitting and negotiating proposals and agreements, outside services required for preparation (statistical consultation, editorial services), and photocopying, binding, and postal or delivery services for proposals. Proposal costs are not appropriate as a direct cost to an existing project, and are explicitly unallowable as direct costs on federal projects. Time and resources spent engaged in these activities should be charged to the appropriate Department Administration Account. In recognition of the effort to identify qualifying expenses, MMRF will rebate 10% of the qualifying expenses charged to these accounts.

Part II: Funded Awards

A. Initiating a Research Project

Work can officially begin on a sponsored project on or after the award's official start date (as indicated on the contract or award statement) OR when an agreement has been fully executed by both parties OR when a binding commitment from a sponsor has been received and the terms and conditions accepted by the MMRF; AND all compliance committee approvals have been obtained. Upon receipt of an award or contract, Grant Administration will assign a new MMRF account number. A "Notice of Award" outlining the responsible parties related to reporting and any special award terms and conditions will be forwarded to the PI to facilitate the setup of the account. If a detailed budget is not included with the award or the proposal data, one will be requested at the time of account establishment. Main budget categories that need to be identified include salaries, fringe, equipment, supplies, and travel.

Work may begin prior to receipt of an award only when pre-award activities are allowed by the sponsor, all compliance requirements have been met, and the PI has requested and received approval to incur project expenses on a "pre-award" basis.

B. Establishing Accounts for Pending Awards

Occasionally, an investigator will need to charge an account for expenses relating to a project which has not yet been officially awarded. For example, a PI may wish to begin a lengthy hiring process before the project's start date. If the PI has received unofficial notice of an award, needs to begin work, and the sponsor allows pre-award costs, the PI may request early access to an account number. To do this, the PI must obtain prior approval from the Office of Grants and Contracts. The PI must, in a letter or e-mail, state the project title, sponsor, anticipated start date, types of expenses to be incurred pre-award, and a declaration of responsibility from the PI (and the appropriate Department Chief, if PI does not have adequate flexible funds to guarantee the project) for the financial obligations to be incurred prior to award.

C. Site visits

Sponsors considering proposals for research programs sometimes conduct site visits or request program reviews by consultants. Office of Grants and Contracts staff are available to confer with site visitors and assist staff in preparations for site visits. The PI or her staff should notify the Office of Grants and Contracts immediately upon request for a site visit from a sponsor.

Part III: Management of Sponsored Projects

Managing sponsored projects requires an understanding of a wide variety of institutional policies and procedures in addition to sponsoring agency requirements. Discussed below are some of the main issues that arise throughout the process.

A. Levels of Responsibility

The Office of Grants and Contracts is responsible for interpreting applicable regulations and sponsoring agency guidelines, developing and maintaining policies and procedures in accordance with those regulations, and providing related training and project management guidance to the MMRF research community. The Office of Grants and Contracts also works with the MMRF Controller and Office of Grant Accounting to develop effective methods to evaluate compliance on an ongoing basis and establish sponsored project accounts in the MMRF's accounting system.

The Office of Grant Accounting is responsible for review of requests for the establishment of accounts in the MMRF's accounting system, and for providing PIs and departmental and programmatic staff with financial information to help fulfill their fiduciary and grants management responsibilities.

PIs are responsible for ensuring the appropriateness of all charges on their sponsored projects, and ensuring the consistent application of direct costing practices to their sponsored projects with the assistance of department staff and/or the Office of Grants and Contracts. It is also the responsibility of the PI to determine, document and justify expenses incurred for their projects. PIs must also take responsibility for any reports due during the terms of a grant, usually consisting of progress updates throughout the project.

B. Principal Investigator Issues

1. PI Account Responsibilities

For audit purposes, project records must document a clear approval trail from the PI for any charge made on an account. Therefore, the Office of Grants and Contracts recommends that the PI, or their designee, sign or initial all account-related papers.

2. PI Effort

Most sponsors assume that PIs have teaching, research, and service-related duties. Federal sponsors will not pay directly for time spent preparing proposals and Federal auditors do not accept the argument that employees may prepare proposals during non-working hours. For these reasons, PIs cannot devote 100% of their effort to sponsored projects without prior institutional approval.

3. Change in PI Status

Sponsors must always be given written notification if the PI takes a long-term leave of absence (usually defined as longer than three consecutive months), leaves the MMRF, or

changes their effort on any project significantly, because the availability of the PI is a key factor in proposal evaluation and award and is required for trials that involve the provision of medical care. These notification letters must be co-signed by the Office of Grants and Contracts before they are sent to the sponsor. Questions regarding these issues should be directed to the appropriate Grant Administrator in the Office of Grants and Contracts.

C. Project Management Issues

1. Sponsor Payments/Cash Receipts

All sponsors should transmit funds directly to the MMRF Office of Grant Accounting. Checks should be made payable to: Minneapolis Medical Research Foundation, Tax ID # 41-1677920. Occasionally, checks are erroneously addressed to PIs or departments. These checks should be forwarded immediately to Grant Accounting for deposit. The check must be accompanied by a memo indicating sponsor, the check number, the MMRF account number (if it has been established), the project title, and the PI's name. This will help ensure that the proper account receives credit.

2. Cost Allowability

Federal Cost Accounting Standards (CAS) requires the MMRF to be consistent in defining, charging, and coding direct and indirect costs to MMRF accounts. Costs for like items in like circumstances must be consistently identified and coded on all accounts, irrespective of the funding source. Those involved in charging costs to MMRF accounts must understand and comply with this policy in order to meet applicable accounting standards and ensure that costs are allocated to accounts in a manner that is an accurate reflection of the expenses incurred.

As a recipient of federal awards, the MMRF is obligated to comply with rules and regulations promulgated by various federal offices. These offices include sponsoring agencies such as the National Institutes of Health and regulatory agencies such as the Office of Management and Budget (OMB). Adherence to these cost principles and practices by the MMRF is necessary to prevent cost disallowances by the federal government. Costs incurred for the same purpose in like circumstances must be treated consistently as either direct or indirect costs across all functions or activities of the institution, unless special circumstances exist.

Federal standards apply four general tests in determining the appropriateness of direct charges to federal projects. These tests require:

1) costs that are reasonable, and can be shown to have a direct benefit to the project. Reasonableness is based on what a "prudent" person would do in the same circumstance;

2) costs that are similar receive consistent treatment, irrespective of the source of funding for the expense;

3) expenses are clearly documented (invoices, receipts, etc.);

4) direct charges are not a part of the institution's indirect cost pool.

3. Cost Transfers on Sponsored Projects

Because of these "tests," it should be obvious why auditors expect that allocation of costs to sponsored projects be made when the cost is originally incurred. The immediacy of the determination "I need this to do that project" lends credibility to the allocation process. On occasion, however, errors are made that must be corrected. The "reasonable and prudent" tests are applicable not only at the time of the original expenditure, but also when moving existing expenses from one project to another. This is the case because the movement of existing charges could be used to circumvent the process of expenditure review and approval, and obscure the inappropriateness of an expense on a particular project, in addition to casting doubt about the care with which original allocation decisions were made.

A Cost Transfer is a direct charge transferred from one account to another after the charge has been posted to the General Ledger. Since costs are expected to be charged to accounts thoughtfully, accurately and in accordance with applicable rules and regulations, original transactions should generally not need correction.

However, in certain circumstances it may be appropriate to move charges from one account to another. A transfer of a cost to a sponsored account is allowed in order to link a cost more appropriately with the benefit it is providing, or to correct an accounting error such as mis-coding. Therefore, cost transfers may be allowable with proper justification, and prior approval from MMRF Grant Accounting. An adequate explanation must be clearly stated on the request form and the PI must certify that the change is true and correct. Due to federal requirements associated with reasonableness and necessity to a project charged, explanations merely stating 'to correct error' or 'to transfer cost' are not adequate.

a. Allowable Cost Transfers

To be acceptable, cost transfers must be timely, allocable to proper budget categories, allowable under sponsor and MMRF policies, and properly documented and approved.

Typical reasons for allowable cost transfers might include the following:

- Errors/Corrections: Cost transfers can be made to correct clerical or accounting errors such as a transposition of numbers.

- Pending Award Costs: If PIs have costs for proposed projects that are expected to be awarded and the sponsor allows pre-award expenditures, costs that have been charged to a non-sponsored account in anticipation of an award (and documented as such at the time of incurrence) can be transferred to the sponsored account.

b. Unallowable Cost Transfers

- Beyond the deadline: Any cost transfer that is requested after 90 days from the original charge will not be allowed. Extenuating circumstances will be reviewed and considered on a case-by-case basis.

- Accounts in over-draft status: Transfer of charges from any account in overdraft status to a federal project is not allowed.

- Expiring accounts with unexpended funds: Cost transfers to a federal project having unobligated balances simply for the purpose of spending down the account, are not allowed.

- Cost transfers to make salary adjustments that do not coincide with certified effort are unallowable.

D. Equipment Ownership

In all instances (except as noted below), when MMRF funds are used to purchase equipment, title of the asset resides with the MMRF. It is the responsibility of the Principal Investigator to track and maintain assets purchased from their funds, and communicate any changes in the disposition or location of those assets to the MMRF Grant Accounting Office. Title to equipment from federal sponsors automatically vests with the MMRF, unless specifically noted in the award document or provided as "government furnished property" in a contract. Most other sponsors allow the MMRF to retain title to equipment purchased for a sponsored project. They usually ask for the right, for up to one year after the end of the project, to request the MMRF to return the equipment. Ownership of equipment is generally addressed in sponsors' guidelines and should be considered when preparing funding proposals.

E. Project Renewal or Closure

If a project cannot be completed by the end of the project period as stated in the award document, the PI may be able to continue the work by requesting an extension.

A "no-cost extension" means that a sponsor will allow the PI an additional period of time, usually no more than one year, to complete the project and file reports, but will not provide additional funding. Requests for extensions must be submitted far enough in advance to allow proper processing by the sponsor prior to the original end date, generally at least 15 days.

Most federal sponsors allow institutions to grant no-cost extensions without prior agency approval if a reasonable and appropriate explanation is submitted to the institution by the PI. The explanation should do the following: describe why the project could not be finished in the planned amount of time; indicate anticipated balances, both direct and indirect; and descritbe how the remaining funds will be used (provide a budget). On

federal projects with expanded authorities MMRF must notify the sponsoring agency of the extension prior to the expiration date.

This information should be forwarded to the appropriate MMRF Grant Administrator. Since not all federal sponsors have delegated authority to institutions to grant no-cost extensions, PIs should contact the Office of Grants and Contracts for information about their particular funding agency. Please Note: Not having spent all the awarded funds is NOT an acceptable reason for requesting a no-cost extension. For sponsors other than federal agencies, contact the Office of Grants and Contracts to determine if extensions are allowed.

Requests for additional no-cost extensions may be considered by some sponsors, but they must be properly submitted through the Office of Grants and Contracts. The Office of Grants and Contracts must certify that the PI's original institutional extension was properly implemented. Most sponsors will not consider any no-cost extension request unless it has been endorsed by the Office of Grants and Contracts.

Part IV - Collaborative Relationships

A. Industry Partnerships

The MMRF is committed to fostering a productive and collaborative relationship with its commercial partners, and its policies reflect its commitment to excellence in research and integrity in its business practices. Agreements with industry (contracts, material transfer agreements, confidentiality agreements, etc.) should be sent to the Office of Grants and Contracts for review, negotiation, and approval. The appropriate Grant Administrator will review the documents for consistency with MMRF policies, and will undertake any negotiations necessary to modify the documents. When providing contractual documents for signature, it is important to provide a description of the work being proposed, an Application for External Support, and the name and telephone number and email address of a sponsor contact name to whom questions/comments can be directed.

General contract provisions that are included in most agreements with industry are outlined below, with information regarding the standard MMRF position on each.

1. Contractual Party

The contractual party in a study agreement must be the Minneapolis Medical Research Foundation (MMRF). The MMRF is the non-profit entity established to administer all research activity on the Hennepin County Medical Center (HCMC) campus.

2. Publication

The MMRF's mission and tax-exempt status require that the results of its scientific research be made available to the public in a timely manner. Therefore, the MMRF always seeks to retain the right to publish independently in order to protect the academic integrity of its researchers and its tax-exempt status. However, in consideration of proprietary issues, we do understand that it is reasonable for a Sponsor to have the right to review and comment on any publication of research results it has supported.

3. Exclusivity

The MMRF will not agree to any exclusive relationships. The establishment of such a relationship may inhibit the academic freedom of the PI or his/her colleagues.

4. Indemnification

The MMRF requires indemnification from its commercial sponsors against claims and/or losses associated with research protocols carried out under its auspices.

5. Confidentiality

The MMRF is equipped to handle proprietary issues such as confidential information; however, in order to ensure that our obligations of confidentiality can realistically be met,

we do ask that confidential information be marked as such. It is also essential that there be no conflict between the definition of confidential material, and the MMRF's right to publish the results of research.

6. Assignment

The MMRF reserves the right to determine with which organizations it conducts business. Therefore, the MMRF will enter into agreements that are assignable to another party only with its prior written consent.

7. Use of Name

The MMRF publishes Activities Reports which describe the work performed at the organization. This information generally includes the Study Name, the Sponsor, the Investigator Name, and the level of funding. The MMRF reserves the right to restrict the use of its name in advertising of any kind.

8. Termination

The MMRF prefers to retain the right to terminate its research study agreements without cause upon 30-days prior written notice.

9. Study Monitoring/Sharing of Research Results

The MMRF requires that the sponsor or monitoring body of clinical studies it conducts to provide information to the MMRF that could affect the safety of participants or their willingness to continue participation, influence the conduct of the study, or alter the Human Subjects Research Committee Approval to continue the study. In addition, when participant safety or medical care could be directly affected by study results, the MMRF secures the contractual right to communicate relevant results to study participants.

B. Conducting Research in HCMC Clinics

Periodically, research projects are planned that will take place in HCMC space and utilize HCMC staff. When this occurs, hospital policy requires that the PI confer with the Manager of the HCMC Department where work will be done as well as the HCMC Compliance Office to determine the appropriate reimbursement for the hospital. Together, MMRF and HCMC have developed a resource utilization and coverage analysis tool for routing requests for access to HCMC resources. The HCMC Resource Utilization Checklist must be approved through the HCMC Compliance Office. This form is included as an Appendix to the HCMC IRB Application, and is available on the MMRF website.

C. Subcontracting to Outside Organizations

A subcontract is defined as the transfer of substantive programmatic work to an outside organization on a sponsored project for which the MMRF is the prime recipient of funds.

It is essential to have a detailed work-scope and budget to clearly define the relationship. The MMRF Office of Grants and Contracts will issue a subcontract agreement to the collaborating institution "flowing down" the appropriate terms and conditions contained in the prime agreement. The information required to initiate a subcontract should be described in the original proposal, and includes the following information:

1. Title of the Project
2. Name of MMRF PI
3. Name of the PI at the Subcontracting Institution
4. A budget for the project
5. A work-scope, or short description of the work to be performed
6. Name/address of institutional official to whom the agreement should be addressed
7. Name/address of Subcontracting Organization

D. Contracting with Consultants/Independent Contractors

There are times when a collaborative relationship develops with an individual outside the organization. That relationship needs to be formalized in order for compensation to be paid. Funds cannot be paid to individuals without a written agreement which outlines the work to be done, the amount of compensation to be paid, and the dates of service. Payments to independent contractors are considered personal income reportable under IRS guidelines on a 1099 form.

There are a number of criteria outlined in IRS policy that must be satisfied in order for an individual to qualify as an independent contractor: 1) the work must be performed independently, and without the direction of the MMRF; 2) the individual must qualify as a business or sole proprietor and be providing similar services to other clients on a regular basis; 3) the work must be performed in a location and with equipment and supplies not provided by the MMRF. IRS rules require that compensation paid must be reasonable for services rendered, and comparable to the benefits received. Staff interested in initiating an Independent Contractor arrangement should contact a MMRF Grants and Contracts Administrator. A copy of the Independent Contractor eligibility checklist can be found on the MMRF website on the Forms page.

E. Contracting for Services with Outside Organizations

The process for contracting with outside organizations is similar to the subcontracting process except that the source of funds originates within the MMRF as opposed to pass through of funds from an outside sponsor. Therefore, the terms and conditions of the relationship follow MMRF policy exclusively, and do not need to take into account any terms and conditions of an outside sponsor. If a Contract for Services is needed, a request/email should be forwarded to the Office of Grants and Contracts outlining the work to be performed and the proposed basis for compensation to be paid.

Part V - Effort Certification

The MMRF's effort reporting system assures external sponsors that funds are properly allocated for the salaries and wages of those working on the projects they support, and provides the means for certifying that the salaries and wages charged to sponsored projects are consistent with the effort expended. All employees involved in certifying effort must understand that funding disallowances and severe penalties, including prosecution under the Federal False Claims Act could result from inaccurate, incomplete, or untimely effort reporting.

The MMRF requires effort certification reports on a monthly basis for HCMC physicians and employees and per pay period for MMRF employees. Each MMRF PI has the primary responsibility to ensure compliance with this policy on their projects. If effort is not properly certified, salary charges cannot be made against a sponsored account.

A. Role of the Principal Investigator

The PIs are responsible for ensuring the appropriateness and accuracy of all effort expended on their sponsored projects. Approval of timesheets and effort reports signify direct knowledge of the work performed, oversight and agreement of the manner in which time was spent, and should be thoughtfully done. In order to be a PI, a minimum amount of effort must be devoted to reflect the PI's scientific and administrative direction of the project regardless of the funding source. On federal projects, the PI is also required to obtain prior approval if absent for more than three consecutive months, or effort is reduced 25% or more from the awarded budget plan. When this situation exists, the PI must contact the federal Grant/Contracting officer to address the following: How does the reduction affect the workscope? If this reduction is related to currently paid effort, how will the funds be re-budgeted?

B. Role of MMRF Employees

When attributing effort to a sponsored project, employees must certify total effort expended on ALL projects. A supervisor or PI may certify individual effort for employees providing they have direct knowledge of the effort performed. The individual employee is responsible for submitting signed certification statements (time and effort forms) to their supervisor on a timely basis.

C. Contributed Effort

Mandatory or voluntary effort expended on one account and paid for by another account (typically a non-sponsored account) is a form of cost-sharing. Mandatory cost sharing is required by certain sponsors and is usually stated in the terms and conditions on the Notice of Grant Award (NOGA) received from the sponsor. Voluntary cost sharing is not required by the funding agency, and represents additional effort expended on that project that is not charged to the project.

E. Effort Distribution

Effort distribution is work performed or the proportion of time spent on any activity and expressed as a percentage of total time. Total effort for an employee must equal 100%. The total institutional appointment (FTE) serves as the basis for an individual's total effort. Effort devoted to sponsored projects must be the determining factor for charging the appropriate salaries and wages to sponsored projects. Charging salaries to sponsored projects that are not supported by certified effort reports is prohibited.

F. Leave of Absence/Vacation and Sick

Any employee who is paid from or contributes effort to a sponsored project during a Leave of Absence must still certify their effort on that project during their leave. Arrangements need to be made for persons away from campus to receive and return required effort documentation.

G. Overtime

Overtime is defined as payments to non-exempt employees for hours exceeding the normal work week (40 hours). Effort should be calculated on the basis of overall hours worked. Overtime can only be charged to federal projects when there are extenuating circumstances. Contact the Office of Grants and Contracts for advice prior to authorizing overtime expenditures on federal projects.

H. Bid and Proposal Effort

Bid and Proposal effort includes the staff time expended in pre-award preparation for a project. This includes writing technical proposals, preparing budgets, and IRB applications. Bid and proposal costs are not appropriate as a direct cost to an existing sponsored project, and are unallowable as direct costs on federal projects. Time spent in pursuit of these endeavors should be certified to the appropriate Department Administration Account (refer to the Proposal Preparation section of this manual).

Part VI - Regulatory Compliance

There are myriad regulatory obligations with which the MMRF research activities must comply including IRS rules, state laws regarding data practices and medical record privacy, and federal regulations. Many of these are referenced throughout this procedure manual. For further clarification, a description of the most frequently applicable laws and policies are described below.

A. Code of Federal Regulations

The Code of Federal Regulations is a codification of the general and permanent rules published in the Federal Register by the Executive departments and agencies of the Federal Government. The Code is divided into 50 titles which represent broad areas subject to Federal Regulation, with subdivisions into chapters which usually bear the name of the issuing agency. The main titles which affect the MMRF are Title 45 - Public Welfare, Title 48 - Federal Acquisition Regulations, and Title 21 - Food and Drug Administration. Search the CFRs at http://www.ecfr.gov/cgi-bin/ECFR?page=browse

Title 45 - Public Welfare contains all current regulations pertaining to the Department of Health and Human Services (not including the FDA), a main source of funding for the MMRF. Title 45 also contains information regarding the protection of human subjects in projects funded by the DHHS. Title 48 - Federal Acquisition Regulations sets forth uniform policies and procedures for acquisition by all federal agencies, and thus is an additional layer of regulation that applies to federal contracts and procurements. Most of the MMRF's federal activity is in the form of grant assistance rather than service procurement, and therefore only a few projects are subject to Title 48. Title 21 - Food and Drug Administration contains the regulations for the activities of the Food and Drug Administration, and outlines the requirements for the protection of human subjects in research (federally-funded or otherwise),in addition to other topics.

B. OMB Circulars

The OMB Circulars pertaining to expenditures of federal awards are promulgated by the U.S. Federal Government's Office of Management and Budget, and were recently combined and consolidated into Title 2 CFR 200, the Uniform Administrative Requirements (Guidance): http://www.ecfr.gov/cgi-bin/text-idx?SID=bf08f42eba435f72b99d19c7bef1cce9&mc=true&node=pt2.1.200&rgn=div5

This regulation sets forth standards for obtaining consistency and uniformity among Federal agencies in the administration of grants to and agreements with institutions of higher education, hospitals, and non-profit organizations.

The audit regulations found at 2 CFR 200 Subpart F, (previously know as the A-133 Audit Circular) set forth the standards among Federal agencies for obtaining consistency and uniformity for the audit of non-Federal entities that expend Federal money. All non-Federal entities (with some exceptions) that expend more than $750,000 per year in federal funds must undergo an annual, external audit every year.

As has been noted previously in this manual, the MMRF expends millions of federal dollars every year, and as such, undergoes an annual audit in conjunction with the overall audit of the MMRF's financial statements. This annual, external audit sets the baseline for many of the MMRF's policies and oversight activities, and is the root of much of the "red tape" that can sometimes feel cumbersome. Following is a discussion of some of the relevant public policy requirements that the MMRF is subject to, and a brief description of how the MMRF meets those requirements. It is provided here to give researchers some context on where the rules that the MMRF enforces come from, and why we take compliance so seriously.

Selected Public Policy Requirements

Debarment and Suspension

The MMRF is prohibited from contracting with any vendor in an amount more than $100,000, or with any subcontractors/subawardees for any amount that have been debarred or suspended from doing business with the Federal government. The MMRF Purchasing Policy outlines this procedure, and the MMRF Office of Grants and Contracts obtains assurance from subawardees that they are not debarred from the Federal Procurement system as a part of the MMRF's standard subcontracting process.

Drug-free workplace

The MMRF enforces a smoke-free/drug free workplace policy. A copy of this policy is available in the Human Resources manual.

Fixed Asset/Property Management

Title to equipment purchased with federal funds (items costing more than $5,000) generally vests with the awardee. However, with this right to ownership comes an obligation for detailed record-keeping and procedures to document internal controls on equipment institution-wide. The MMRF maintains a fixed asset policy that requires a physical audit of Federal assets bi-annually, so if you have purchased equipment on a federal award, you can expect to see a member of MMRF's accounting staff come by to tag your assets when you purchase them, and a visit from them every other year to do the inventory.

Freedom of Information Act (FOIA)

Certain Federal MMRF activities are subject to FOIA disclosure requirements. If the MMRF were asked to provide information under FOIA related to those activities, it would be required to do so. On occasion, especially if there are intellectual property concerns with regard to work being proposed, researchers seeking federal funding may find it prudent to mark their works submitted to the Federal government as confidential. It is important to know that information contained in proposals to the Federal government is considered available under FOIA once a proposal is funded (but not until such time) and that there is the possibility that those documents may be requested under FOIA.

Lobbying

The federal government has a disclosure requirement for institutions that engage in lobbying, and paying for the cost of lobbying is strictly forbidden on federal awards. It is important for investigators to know that the MMRF has a policy against lobbying and does not engage in those activities.

Public Disclosure

The MMRF's stated mission and IRS tax-exempt status require that our work benefit the public. A significant component of that benefit is accomplished through scientific publication. The MMRF publishes an Annual Report describing our work with a list of publications and list of research projects being undertaken each year.

Inclusion of Women/Minorities as Subjects in Clinical Research

Proposals submitted to the National Institutes of Health require a description of how women, children, and minorities will be included in the research being proposed. If the inclusion of these groups is not scientifically feasible, a rationale justifying their exclusion must be included in the proposal. It is important for investigators to know that if this requirement is not addressed in federal proposals, they may be returned without review for non-responsiveness.

Sub-recipient Monitoring
There are several factors that go into the determination of what level of monitoring is required for subcontractor activity. The main criteria are as follows:

-Do we have a previous relationship with the institution?
-Are they known a research entity (i.e. universities)?
-Has a previous collaboration established their competence at managing federal funding?
-Are their audit reports free of significant findings?

Based on the above criteria, the MMRF Grant Administrator determines the Subcontractor's level of experience as recipients of federal funding as both Prime and/or subrecipients. Depending on the outcome of the analysis, the MMRF may request additional documentation from a subcontractor, or an MMRF representative may meet with the subcontractor from time to time to review compliance requirements and, if necessary, may visit the site of the subcontractor to review records and reports.

C. Other Sponsoring Agency Regulations

In general, each agency or organization making awards for research publishes its own set of specific guidelines and requirements. For federal agencies, these documents do not supersede the Circulars, but serve to further clarify how that particular agency is interpreting and implementing the rules described in the Circulars. It is essential for PIs

and their designated staff responsible for the management of research projects to have an understanding of their particular agencies guidelines.

D. Applying for Compliance Committee Approvals

1. Human Subjects

Activities involving the use of human subjects must conform to the standards set forth in the MMRF's Assurance of Compliance with HHS Regulations for the protection of Human Subjects. To ensure this occurs, the Human Subjects Research Committee must review and approve all protocols for the use of human subjects. Forms, guidelines, and contact information for submission to the Committee are available on the MMRF website. A completed application, protocol, and informed consent document should be submitted to the Office for Human Subjects Research prior to initiating any human subjects' research. Under no circumstances may human subjects' research begin until approval from the IRB has been secured. Maintaining approval on continuing projects is the responsibility of the PI. Notice of final approvals must also be submitted to the Office of Grants and Contracts.

2. Animal Approval

All activities involving vertebrate animals must conform to the standards set forth in the MMRF's Animal Welfare Assurance policy. The Institutional Animal Care and Use Committee (IACUC) must review and approve all protocols involving the use of vertebrate animals. A completed Animal Usage Form should be completed and forwarded to the Laboratory Services Coordinator. Approval by the IACUC Committee is required prior to any work beginning. Maintaining approval on continuing projects is the responsibility of the PI. Notice of final approval must also be submitted to the Office of Grants and Contracts.

3. Conflict of Interest

It is recognized that the involvement of individuals in outside professional activities, both public and private, often serves not only the participants, but also the MMRF and society at large. It is assumed that individuals will be alert to the possible effects of outside activities on the objectivity of their decisions, and the fulfillment of their obligations. The MMRF Conflict of Interest Policy requires disclosure of relevant personal interests, and review and approval of such interests, depending on level of involvement in a given situation. Those levels of interest, and the policies and procedures related to disclosure, are defined in the MMRF Conflict of Interest Policy. Assurance is given upon signature of the PI on the Application for External Support that consideration has been given and necessary disclosures have been made.

4. Hazardous Materials

If you will be working with a project that involves hazardous materials or select agents (chemicals, radioactive isotopes, blood borne pathogens, and infectious waste) you must

contact the MMRF Institutional Biosafety Committee via the MMRF Laboratory Coordinator.

Part VII - General Accounting Procedures

The MMRF has established an internal accounting control structure that provides assurance that assets are safeguarded against loss from unauthorized use or disposition. This structure ensures that financial transactions are executed in accordance with applicable regulations, sponsor guidelines and management authorization, and recorded properly to permit the preparation of financial statements in accordance with Generally Accepted Accounting Principles (GAAP).

MMRF also publishes a separate expense manual presenting detailed guidelines for incurring non-payroll expenses in the MMRF. This manual is available from MMRF Accounting and on the MMRF website, and contains important and helpful information for any employee responsible for assigning expenses to MMRF accounts.

A. Expenditure Routing and Approval

All expenditures incurred must conform to the stated mission of the organization. For clarification, the mission statement is provided below.

"The mission of the MMRF is to improve patient care and the health of our community through research and education."

1. Processing Invoices

To initiate payment for an invoice when no purchase order was obtained, an orange "check request" form must be completed and submitted to MMRF Grant Accounting for approval. The original invoice must be attached, and a clear description of the benefit to the project being charged must be reflected on the check request. The check request must also be signed by the PI responsible for the account, or his/her designee. If there is a supply or equipment purchase to be made in the future, complete an MMRF Purchase Order form so that MMRF Purchasing can procure the item.

2. Processing Travel Reimbursement

Research Investigators, MMRF employees, and others may be authorized to attend institutes, scientific meetings, or training programs, subject to the availability funds, when it is determined that such attendance is within the scope of MMRF's mission, and approved by the appropriate Principal Investigator and/or Division Head. Travel must be pre-authorized, and must be at least 50 miles away from MMRF in order for reimbursement of lodging, meals, and other incidental expenses to be allowable as "travel". Travel to be funded by sponsored projects should be carefully planned to ensure it is permissible and reimbursable.

Cash advances are not available. An individual who is seeking reimbursement for travel on MMRF business must give an accounting of actual expenses incurred on a Travel Reimbursement Form within 60 days of the last day of the trip. Only actual, necessary, and reasonable expenses will be reimbursed. Original, itemized receipts are required for

any expense in excess of $25. Less than first class air accommodations shall be the standard mode of travel.

MMRF does hold an account with Travel Innovations, Wayzata, MN, 952-476-1100. Feel free to contact Travel Innovations to have them reserve flights for you. Attach their invoice to a completed Travel Reimbursement form (made out to Travel Innovations), so that MMRF accounting can pay via the appropriate accounts associated with that trip on the travel authorization form.

B. Account Reconciliation

Monthly expenditure reports are distributed by MMRF Grant Accounting. It is recommended that monthly expenditure reports be carefully reviewed in a timely manner, and reconciled against documentation in the department. Discrepancies should be called to the attention of the Grant Accounting Supervisor immediately upon their discovery.

C. Charging Salaries to Sponsored Projects

MMRF and HCMC staff needs to communicate how their time is spent in order for accounting to distribute funds appropriately. These forms essentially tell accounting how you will be paid.

MMRF staff certifies their research effort and charge salaries bi-monthly (per pay period) on "Employee Effort Certification Forms" which are signed by the employee and countersigned by a supervisor with direct knowledge of their effort expended. These forms are due at the end of every pay period, so after the 15th and last day of every month.

HCMC physicians and Staff certify their research effort and charge their salaries monthly on "Effort Certification Reports" generated by MMRF Grant Accounting, and forwarded to the individual PIs for verification and signature. The effort level reflected on these reports is the effort reflected in the approved budget or project proposal. If changes need to be made to the effort levels on these reports, they should be made manually by the investigator prior to signing. If the change is permanent, a memo should be submitted to MMRF Grant Accounting so the change can be verified, if necessary, and the reporting system can be updated. Physicians have the option of charging their salaries up to the total amount certified to their projects. This is done by marking the appropriate check box on the certification forms.

D. Deficits

MMRF research activities may not operate in deficit or exceed a sponsor's budget, except for sponsored research accounts that contractually result in an expenditure of funds before reimbursement is received. If an account goes into deficit, the account will be reviewed by MMRF Accounting staff, and put on delinquent status if one of the following conditions exists:

-Expenses have exceeded available budget
-Terms of the contract have been violated
-No contract exists
-The account is non-sponsored with no outstanding cash receipts

Appropriate MMRF staff will be assigned to investigate and resolve issues associated with delinquent accounts. If the deficit is not resolved by this action, the PI will be notified in writing that an acceptable financial plan to resolve the deficit must be submitted in writing within 60 days. Failure to submit an acceptable financial plan (as determined by the MMRF Finance Committee) will result in the following actions: No new expenses will be allowed on the account; all personnel charged to the account will be "work-force reduced" and placed on an "on-call" status; available non-sponsored funds under the direction of the PI will be used to clear the deficit; if sufficient funds are not available, the Department Chief will be contacted by the Finance Committee to resolve the deficit fund balance.

Part VIII - Miscellaneous

A. Space Issues

All rent and operating expenses in the MMRF are allocated as direct costs based on occupied square footage. Rentable square footage has two components: occupied square footage and an allocation of common space (i.e., bathrooms, meetings, hallways, common equipment areas, etc.). The determination of who is responsible for specific areas is coordinated through the MMRF Space Committee. Formal written requests for new space must be communicated through the MMRF Space committee via the MMRF Vice President of Operations. If you are vacating space, you must complete a form, "Procedures for Vacating a Research Laboratory." This form and instructions is available on the MMRF website.

When budgeting for rent for sponsored projects, contact the MMRF's Financial Services Manager. You must know the precise location of the space you are planning to use. Grant accounting will calculate the approximate rent and operating expense using an expense allocation matrix, and will assist investigators in the development of a budget justification for the cost. Other questions related to space should be directed to the Vice President of Operations.

B. Staff Hiring/Human Resources

When it is determined that a new position needs to be filled, the supervisor responsible for managing the new position should contact MMRF Human Resources to initiate a requisition. An employee requisition is required for all new, replacement, or upgraded positions. A requisition involving an employee on a sponsored project requires the signature of the PI. Before a position can be posted, the account number to be charged for both the cost of the advertising, and the project(s) paying the salary for the position must be noted on the requisition. Human Resources will handle the posting and recruitment for the position, and can provide assistance in determining an appropriate job class, if needed. In general, Human Resources will do the initial applicant screening and interviews, and provide appropriate applications to the Department for review. Following interviewing, the Department and Human Resources will meet to determine if a job offer will be made, and discuss any unresolved issues related to the new hire.

C. Information Systems

The goal of the MMRF Information Systems department is to provide computer support for administrative personnel. Currently, the service is limited to the administrative section. Services include centralized systems for grant management/accounting and development, networking, internet access, software and hardware support, data management, and training.