

**Minneapolis Medical Research Foundation  
Sponsored Project Administration**

**Guidance and Procedures**

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## **Introduction**

### About the Organization

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 currently ranks nationally in the top 7% 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 all 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 \$20 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. Policies are developed and implemented through an infrastructure of committees, including the MMRF Executive Committee, the MMRF Finance Committee, the Scientific Advisory Committee, the HFA Executive and Finance Committees, and the HFA Board of Directors.

The MMRF is a supporting organization to Hennepin Faculty Associates, the multi-specialty physician practice plan which serves the Hennepin County Medical Center. The MMRF's non-profit 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.

Hennepin Faculty Associates (HFA) is a non-profit physician practice plan with approximately 300 members. HFA physicians hold adjunct academic appointments with the University of Minnesota Medical School. The affiliation agreement governing this relationship is between the Hennepin County Board of Commissioners (who provide for the establishment of the Hennepin County Medical Center), and the Board of Regents of the University of Minnesota.

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.

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. Additional detailed information can be obtained in the "Sponsored Project Administration Workshop Training Materials" developed by the MMRF Office of Grants and Contracts, and other reference materials noted in the Appendix. 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 MMRF publications such as the *MMRF Update* and *Connections*, and the MMRF website.

Workshops are held at regular intervals, and training materials can be obtained from the Office of Grants and Contracts upon request. An outline of the topics available is presented in the Appendix. Questions regarding specific parts of this manual should be directed to the Office of Grants and Contracts, or a relevant contact listed in the Appendix.

## **Part I: Proposal submission**

A Sponsored Project is a financial award from an external agency for the conduct of a specific scope to 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. Gifts are handled by the MMRF Development Office, and questions regarding gifts should be directed to the Vice President of Development.

Submission of a proposal to an outside agency generally requires an institutional signature, 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.

### **A. Compliance Approvals**

The MMRF requires a cover form, an "Application for External Research" 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 Research" may be duplicated from the Appendix copy, or is available through the Office of Grants and Contracts.

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. Although compliance committee approvals may not be required at the time of proposal submission (and are therefore pending), they must be obtained prior to the commencement of work, and/or the expenditure of funds on the 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, if adequate notice is provided prior to a submission deadline.

It is important to be aware that HCMC employees are not considered “personnel” of the MMRF, and budgeting for the cost of their participation should be handled as an “other” expense as a separate line item. Also, fringe rates for physicians employed by HFA vary from person to person. The overall MMRF institutional fringe rate should not be used for HFA physicians, and their individual fringe rates should be confirmed with HFA payroll at the time of budget development.

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 Controller on the “MMRF Rate Sheet.” It is recommended that rates be confirmed with the Controller or a Grant and Contract Administrator via telephone for each proposal.

### 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 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:

- 1) Federal rates are applied to the salaries and wages of federally funded research projects, and are set based on negotiation with the federal government.
- 2) Industry rates are applied to revenues/cash receipts received from commercial organizations under contract, and are set by MMRF Board of Directors.
- 3) 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. For instance (this is not the current rate), for a project with \$100,000 in budgeted salaries, an additional \$35,000 (35% of salaries and wages) should be included for institutional indirect 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 call 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.

## 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 its direct costs.

When calculating overhead on a cash receipts basis, determine the total direct costs necessary to complete the work proposed, 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 ( $\text{Direct Costs}/1 - \text{Overhead Rate} = \text{Total Costs}$ ). 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.

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 other documentation (copies of bylaws, verification of tax-exempt status, etc.) may be necessary. While most standard information is on file at MMRF, some documentation (such as certificates of insurance) require 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 unallowable as direct costs on federal projects. Time and resources spent in pursuit of these endeavors 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 set up 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, a PI needs 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 write a letter to the Office of Grants and Contracts stating the project title, sponsor, anticipated start date, types of expenses to be incurred pre-award, and a declaration of responsibility from the PI for the financial obligations to be incurred prior to award. A sample pre-award letter can be found in the Appendix.

### 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 a departmental Project Coordinator and/or the Office of Grants and Contracts. It is also the responsibility of the PI to determine, **document and justify** incurred for their projects.

#### **B. Principal Investigator Issues**

##### **1. PI 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.

### 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), or leaves the MMRF, because the availability of the PI is a key factor in proposal evaluation and award. These 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 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) require 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) that costs 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) that costs that are similar receive consistent treatment, irrespective of the source of funding for the expense;
- 3) that expenses are clearly documented (invoices, receipts, etc.);
- 4) that direct charges are not a part of the institution’s indirect cost pool.

### 3. Cost Transfers on Sponsored Projects

Because of the foregoing “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 (please see Appendix for Asset Disposition Form). 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 60 to 90 days.

Most federal sponsors allow institutions to grant no-cost extensions if a letter of request and explanation is submitted to the institution by the PI. The explanation should: describe why the project could not be finished in the planned amount of time; indicate anticipated balances, both direct and indirect; and how the remaining funds will be used (budget). On federal projects with expanded authorities **MMRF must notify the sponsoring agency of the extension prior to the expiration date.**

The letter 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. **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.

A request for a second 12-month no-cost extension may be considered by some sponsors, but it too 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 requested and exhausted. Most sponsors will not consider any no-cost extension request unless it has been signed and submitted through 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 industrial 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 Research, and the name and telephone number of a sponsor contact 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 retains the right to publish independently in order to protect the academic integrity of its researchers and its non-profit status. However, in consideration of proprietary issues, we do understand that it is necessary 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 industrial 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 an Activities Report which describes the work performed at the organization over the previous year. This information 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

Often 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 with which he/she will be working to negotiate appropriate reimbursement for the hospital. HCMC has developed a Resource Utilization Checklist 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 in this manual in the Appendix.

#### C. Conducting Research in HFA Clinics

It is important to consider the cost of clinic space and HFA clinic personnel when budgeting projects to be done in HFA clinic space. The PI responsible for the research work being performed should notify the appropriate HFA Clinic Manager to confirm the availability of clinic space and staff, and make arrangements for payment for their use. It is also important for the PI to notify the HFA Clinic Billing Manager of any arrangements that are made related to research in HFA clinic space, so improper research related charges are not passed on to patients or third-party payers.

#### D. 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

#### E. 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 the MMRF Controller. A copy of the Independent Contractor Agreement and checklist can be found in the Appendix.

#### F. 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 used to pay for the work 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 written request should be forwarded to the Office of Grants and Contracts which outlines the work to be performed and the 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 HFA physicians and per pay period for MMRF employees. Each MMRF PI has the primary responsibility to ensure compliance with this policy. 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. Signature on time sheets and effort reports signify direct knowledge of the work performed, review and approval 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 he/she will be absent for more than three consecutive months, or his/her effort is reduced 25% or more from the awarded budget plan. When this situation exists, the PI must write a letter to the federal grant contracting officer addressing the following: How does the reduction affect the work-scope? If paid effort, how will the funds be re-budgeted? The letter must be signed by the PI and endorsed by the Office of Grants and Contracts.

### 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 sheets) to their supervisor on a timely basis. An example of an appropriately certified time sheet is attached in the Appendix.

### 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 a myriad number of 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. Copies of these documents are available for reference in the Office of Grants and Contracts. Most can also be accessed on the World Wide Web.

### 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 web address [www.access.gpo.gov/nara/cfr/index.html](http://www.access.gpo.gov/nara/cfr/index.html).

*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 are promulgated by the U.S. Federal Government's Office of Management and Budget, and are incorporated into the Code of Federal Regulations, Title 45. Those specific parts applicable to the activities of the MMRF are outlined below. The specifications outlined in these Circulars are applicable only to federally-funded projects.

1. OMB Circular A-110 - Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and other Non-profits

This Circular 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 other non-profit organizations. The provisions of the sections of this Circular are applied by Federal agencies to recipients and sub-recipients, as applicable.

2. OMB Circular A-122 - Cost Principles for Non-profit Organizations

This Circular establishes principles for determining costs of grants, contracts and other agreements with non-profit organizations. The principles are designed to provide that the Federal Government bear its fair share of costs except where restricted or prohibited by law.

3. OMB Circular A-133 - Audits of State, Local Governments, and Non-profit Organizations

The A-133 Circular sets 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 \$300,000 per year in federal funds must undergo an A-133 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 A-133 audit in conjunction with the overall audit of the MMRF's financial statements. The A-133 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 investigators find so 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/HFA 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 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, 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, and a significant component of that benefit is accomplished through scientific publication. The MMRF publishes an Annual Report describing our work, and one of the pieces of the Annual Report is a list of publications, and a 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 now 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 previous collaboration established their competence at managing federal funding?
- Are their A-133 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 in the Appendix. 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 with 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 Research 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, 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 manual presenting detailed guidelines for incurring non-payroll expenses in the MMRF. This manual is available from MMRF Accounting, and contains important and helpful information for any employee responsible for assigning expenses to MMRF accounts.

### A. Expenditure Routing and Approval

All expenditures incurred by the MMRF must conform with 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. Purchasing

Purchasing and materials management services are provided to the MMRF under a shared support service arrangement with the parent organization, Hennepin Faculty Associates (HFA).

#### 2. Purchase Orders

To initiate a “purchase order,” a blue requisition needs to be completed and forwarded to HFA purchasing. These blue requisition forms can be obtained from the HFA Storeroom, and a sample is provided in the Appendix.

#### 3. 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 (see sample in the Appendix). 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.

#### 4. 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 (see Appendix for form), and must 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 allowable. 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. Receipts are required for any expense in excess of \$25. Less than first class air accommodations shall be the standard mode of travel.

#### B. FAS/Cost Point Reports

The MMRF Fund Accounting System (FAS) is an in-house developed system designed to meet the special accounting needs associated with grants, contracts, industry studies, and general research and education activity. The system gives special consideration to the reporting needs of investigators, internal controls that ensure the integrity of the information, and efficiencies that result in timely and complete information.

#### C. 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.

#### D. Charging HFA Physician Salaries to Sponsored Projects

HFA physicians certify 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.

#### E. 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:

1. Expenses have exceeded available budget
2. Terms of the contract have been violated
3. No contract exists
4. 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 are included in the Appendix.**

When budgeting for rent for sponsored projects, contact MMRF’s Grant Accounting Supervisor. 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 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.

Existing employees interested in applying for a new position within the MMRF should contact Human Resources for an internal application, and additional information.

### C. Development

The MMRF Office of Development handles gifts, memorials, gifts-in-kind, stock gifts, and event sponsorships from individuals, corporations and foundations.

#### D. Corporate Communications

The MMRF Office of Corporate Communications handles both internal and external communications. It is responsible for producing many MMRF publications including the *MMRF Activity Report*, *Research Connections* newsletter, *Update* internal newsletter, general brochures and collateral materials. Corporate Communications also is responsible for public and media relations, and the MMRF web site ([www.mmrfweb.org](http://www.mmrfweb.org)). If you have communications needs or suggestions, please contact the Corporate Communications Office.

#### E. 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.

## Part IX - Appendices

A. Contacts

B. Forms/Templates (*Appendix B not available electronically*)

Application for External Research  
Check Request Form  
Cost Transfer Request Form  
HCMC Resource Utilization Checklist  
Human Subject Protection Researcher Training Verification  
MMRF Travel Forms  
Independent Contractor Form  
IRB Application  
MMRF Inter-departmental Service Agreement Template  
Procedures for Vacating a Laboratory Form  
Requisition  
Sample Letter of Intent  
Sample No-Cost Extension Letter  
Sample Pre-award Request  
Sample Time Sheet with Appropriate Effort Certification Format  
Sample Budget Format – Standard PHS Format  
Sample Budget Format – Costing out Per Procedure/Per Patient

C. MMRF Research Management Workshop Training Topics

D. Other Important Reference Materials Available

1. MMRF Human Resources Manual
2. MMRF Policy and Operations Manual
3. MMRF Safety Manual
4. MMRF Non-payroll Business Expense Guidelines

## **Appendix A**

### **Helpful Contacts**

<u>Contact Name/Department</u>	<u>Telephone Number</u>
MMRF Chief Operating Officer – Mary Emmons Bergaas	347-5098
MMRF Controller – Mike Krekelberg	347-5130
MMRF Human Resources – Cathy Tikkanen	347-5306
MMRF Manager, Financial Services – Vicki Hammerstrom	347-5131
MMRF Manager, Grants & Contracts – Kim Miller	347-5099
MMRF Grants & Contracts Administrator – Ellen Davis	347-8754
MMRF Grants & Contracts Administrator – Mary Bicknese	347-4855
MMRF Grants & Contracts Administrator – Joshua Humphrey	347-7799
MMRF Grants & Contracts Administrator – Carey Nadeau	347-6852
MMRF Grants & Contracts Administrator – Bonnie Crissman	347-5991
MMRF Assistant Grants & Contracts Administrator – Katie Phalen	347-7618
MMRF Veterinary Services – Allison Jarvis	347-4411
MMRF Payroll – Kathy Neubauer	347-5129
MMRF Travel Coordinator – Lisa Hedberg	347-5119
HFA Clinic Billing – Carol Rontti	347-5058
HFA Purchasing – Tiffany Ernst	347-5095
HFA Storeroom – Bill Handt	347-4484
HFA Payroll – Mary Hlavinka	347-5127
HFA Facilities – Robbin Lehrman	347-5138
Human Subjects Committee – Sharyn Aasen	347-8528
MMRF Director of Clinical Trials Training – Carla Erickson	347-5967
MMRF Grant Accountant – Megan Crosby	347-4414
MMRF Effort Coordinator – Marie Lynch	347-5106
MMRF Laboratory Coordinator – Carolyn Erickson	347-7370

# **Appendix B**

## **Forms/Templates**

**APPENDIX C**  
**MINNEAPOLIS MEDICAL RESEARCH FOUNDATION**  
**RESEARCH MANAGEMENT WORKSHOP TOPICS**

**Module I. Sponsored Project Administration - Guidance and Procedures Manual**

- Part I) Proposal Submission
- Part II) Funded Awards
- Part III) Management of Sponsored Projects
- Part IV) Collaborative Relationships
- Part V) Effort Certification
- Part VI) Regulatory Compliance
- Part VII) General Accounting Procedures
- Part VIII) Miscellaneous
- Part IX) Appendices

**Module II. Research Proposal Development (*complements Part I of SPA Manual*)**

- A. Seeking out Funding Sources
  - 1) Types of Sponsors
  - 2) Searching On-line
  - 3) Developing Relationships with Potential Sponsors
  
- B. Scientific Proposal Preparation
  - 1) Protocol Development
  - 2) Proposal and Study Timelines
  - 3) Subject Recruitment and Study Planning
  - 4) Industry Studies
  - 5) Clinical Trials
  
- C. Business Proposal Preparation
  - 1) Budgeting for individual line items
  - 2) Other support
  - 3) Budget Justifications
  - 4) Budgeting for Per Patient Studies
  - 5) PHS 398

**Module III. Important Considerations for Sponsored Research Projects**

- A. Legal Issues (*complements Part IV of SPA Manual*)
  - 1) Publishing
  - 2) Intellectual Property
  - 3) Contract Negotiation and Terms
  - 4) Unrelated Business Income (UBIT) and Tax-Exempt Status
  
- B. Regulatory Compliance (*complements part VI of SPA Manual*)
  - 1) OMB Circulars
  - 2) PHS/NIH Grants Policy Statements
  - 3) Code of Federal Regulations
  
- C. Responsible Conduct of Research
  - 1) Ethical Principles and Guidelines
  - 2) Behavior Standards/Scientific Misconduct