

## **REQUIREMENTS FOR FINANCIAL AND BUSINESS MANAGEMENT SYSTEMS FOR SBIR/STTR AWARDEES**

If the pending application is funded, the organization must have written policies and procedures for the following financial and business management systems and must follow those policies and procedures. **It is important for the organization to be aware that an awardee's failure to follow the applicable laws, regulations and policies in the National Institutes of Health Grants Policy Statement (NIH GPS), December 2003, could result in audit disallowance, suspension, and/or termination of an award(s) and could jeopardize any future funding. This includes, but is not limited to, compliance with the policies, procedures and systems described below.** (To view the links contained in this document, you must download the Adobe Acrobat Reader, Version 6.0.1)

The electronic copy of the NIH GPS is available at:

[http://grants1.nih.gov/grants/policy/nihgps\\_2003/index.htm](http://grants1.nih.gov/grants/policy/nihgps_2003/index.htm)

Also, a PDF version of the NIH GPS will be available from this location. Hard copies are not available. The section devoted to for-profit organizations is located on page 237. Website:

[http://grants.nih.gov/grants/policy/nihgps\\_2003/NIHGPS\\_Part13.htm#\\_Toc54600282](http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part13.htm#_Toc54600282)

Information regarding prior approval requirements is found in the NIH Grants Policy Statement at page 105.

Website:

[http://grants.nih.gov/grants/policy/nihgps\\_2003/NIHGPS\\_Part7.htm#\\_Toc54600129](http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part7.htm#_Toc54600129)

The awardee must have records that document and reflect compliance with the following:

### **General Information**

1. The organization meets the criteria to qualify as a "small business," as defined in the Omnibus Solicitation for SBIR/STTR Grant Applications.
2. Lines of authority and responsibility of officers and key personnel (i.e., organization chart).
3. Recent audits by a government agency and/or independent public accountant other than financial statements (Clarification of Audit Requirements of For-Profit Organizations Including SBIR/STTR Grantees, Attachment #1).
4. Names of officials with authority to sign for the organization.

### **Financial Stability**

1. The most recently audited financial statement; or if the organization does not have an audited financial statement, a current balance sheet.
2. If the working capital ratio (total current assets divided by total current liabilities) on the financial statement or balance sheet is less than 1:1:
  - a) A cash flow forecast for the organization covering the entire budget period.
  - b) A bank line of credit or other source of funds that could be accessed to cover working capital shortages.
  - c) Information regarding any outstanding loans.

NIH SBIR/STTR website for Financial Systems Requirements (short evaluation) at:

[http://grants1.nih.gov/grants/funding/pol\\_fin\\_eval.html](http://grants1.nih.gov/grants/funding/pol_fin_eval.html)

## Financial and Administrative Systems (full evaluation)

NIH Grants Policy Statement December 2003, page 120. Website for financial and management systems: [http://grants.nih.gov/grants/policy/nihgps\\_2003/NIHGPS\\_Part7.htm#\\_Toc54600136](http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part7.htm#_Toc54600136)

### Accounting System

Is a double-entry system.

1. Maintains the basic books of account; e.g., cost journal, general ledger, project ledger, chart of accounts (sample Attachment #2).
2. Identifies individual receipts and expenditures for each grant or contract.
3. Maintains a separate ledger for indirect costs and separate ledgers for each project.
4. Maintains documents supporting accounting entries; e.g., purchases orders, vouchers, vendor payments, etc.
5. Records expenditures for each program by required budget cost categories.
6. Provides for the timely billing and payment of accounts receivable and payable.

### Internal Controls

1. All accounting entries are supported by appropriate documentation.
2. An authorized official approves all checks before they are signed.
3. All checks are prenumbered and accounted for when the general-purpose bank account is reconciled.
4. Safeguards are in place to prevent misuse of any petty cash funds.
5. Employees who handle funds are required to be bonded against loss by fraud or dishonesty. For further information on insurance see NIH Grants Policy Statement, December 2003, page 92. Website: [http://grants2.nih.gov/grants/policy/nihgps\\_2003/NIHGPS\\_Part6.htm](http://grants2.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part6.htm)

### Personnel

1. How salary levels are established; e.g., comparability survey (*Employee compensation should be comparable to the compensation for employees with similar skills in the same geographical area*).
2. Salaries of personnel supported by Government projects are not higher than salaries of personnel in similar positions supported by the institution's funds.

### Time and Effort Reporting

A written policy on the time and effort reporting system for professional and nonprofessional staff, including the position of staff approving/certifying time and effort and the frequency of the after-the-fact certification process. *NOTE: Commercial (for-profit) organizations must document salaries and wages charged to contracts and grants by maintaining a labor distribution system for all employees regardless of function. The labor distribution system must account for total hours and charge direct and indirect labor to the appropriate cost objectives in order to accurately identify labor costs: 1) charged to direct projects; 2) charged to indirect activities; and 3) included in the base to which indirect costs are allocated.* ("Time and Effort Reporting for Commercial Organizations Policy," Attachment #3; Sample Timesheet <http://grants1.nih.gov/grants/funding/timesheet.pdf>, Attachment #4).

### Consultant Services (if applicable)

1. A written policy must describe the internal process for establishing the need for consultants, their selection, and the rates to be paid. Procedures must require consultants to sign consulting agreements outlining services to be rendered, duration of engagement, pay rates, and procedures for monitoring or reporting progress. These agreements should also address compliance with applicable Federal regulations and NIH policies.
2. The organization must be able to support charges for consultants to grants with documentation and information required in the NIH Grants Policy Statement, December 2003, page 89. Website: [http://grants2.nih.gov/grants/policy/nihgps\\_2003/NIHGPS\\_Part6.htm](http://grants2.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part6.htm). See Attachment #5 for sample policy.

### **Equipment/Property Management System**

Property records that outline the description, cost, including information necessary to calculate the percentage of Federal participation in the ownership, acquisition date, source of property, location, use and condition, and ultimate disposition data.

1. Written procedures for screening proposed purchases of equipment to avoid unnecessary or duplicate purchases.
2. Identification procedure for tags or labels on equipment purchased with Federal funds to indicate Government ownership and a records system that identifies the grant under which the equipment was acquired.
3. Written procedures for identifying equipment purchased with Federal funds and for conducting an annual physical inventory of equipment.
4. Controls to ensure adequate safeguards to prevent loss, damage, or theft of the equipment.
5. Maintenance program to keep the equipment in good use and working condition.

*NOTE: Title to equipment acquired by a recipient with grant funds is vested in the recipient. The management, control, and disposition of property will be governed by the rules and regulations which are set forth in 45 CFR Part 74.34. Further information is available upon request from the Chief, Property Accountability Section, Personal Property Branch, NIH; Telephone: (301) 496-6467; FAX: (301) 496-8428. See NIH Grants Policy Statement, December 2003, page 124. Website:*

[http://grants2.nih.gov/grants/policy/nihgps\\_2003/NIHGPS\\_Part8.htm#\\_Toc54600139](http://grants2.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part8.htm#_Toc54600139). See Attachments #6 and #6a for sample purchase order form and policy.

### **Travel (if applicable)**

1. Written travel policies that comply with requirements in the NIH Grants Policy Statement, December, 2003.  
*NOTE: If there is no written travel policy, Federal Travel Regulations must be used, including the maximum per diem rates and subsistence rates prescribed in those regulations, to determine the amount for travel costs.*
2. Written travel requests that show the purpose of the trip and that are reviewed and approved by an authorized organizational official prior to the trip.
3. Receipts are required for lodging and meals if reimbursement is based on actual costs.

*NOTE: Regardless of organizational policy, for-profit organizations may not charge travel cost to grants that exceed Federal travel limitations. The GSA Federal Travel Regulations are available on the internet, with all Amendments. Website: <http://www.gsa.gov>. See Attachment #7 for sample policy.*

### **Consortium Arrangements (if applicable)**

A written inter-institutional agreement with consortium institutions that complies with the NIH requirements for consortium agreements which are set forth in the NIH Grants Policy Statement, December 2003, page 224.

Website: [http://grants2.nih.gov/grants/policy/nihgps\\_2003/NIHGPS\\_Part12.htm#\\_Toc54600251](http://grants2.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part12.htm#_Toc54600251), including written procedures for monitoring compliance with Federal regulations and NIH Policies at cooperating institutions if research involving human subjects or live vertebrate animals is being conducted at cooperating institutions. See Attachment #8 for sample policy.

### **Procurement**

A written policy that addresses, at a minimum, the following:

1. Who has the responsibility for purchasing.
2. Purchase orders for all equipment and services, which identifies project number associated with purchase.
3. How quality, cost, source selection, etc., are considered.
4. How partial deliveries are handled.
5. When competitive bids are required.
6. How invoices are checked and authorized for payment.
7. The procedure to screen subcontractors to insure that debarred or suspended individuals or entities are not utilized. List of Parties Excluded from Federal Procurement and Nonprocurement Programs may be found at website: <http://www.epls.gov/>.

8. Procedures that assure that minority firms, women-owned firms, and labor surplus area firms are used whenever possible as required in NIH Grants Policy Statement, December 2003, page 128.

### **Program Income (if applicable)**

NIH Grants Policy Statement, December 2003, page 121. Website:

[http://grants2.nih.gov/grants/policy/nihgps\\_2003/NIHGPS\\_Part8.htm#\\_Toc54600138](http://grants2.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part8.htm#_Toc54600138)

1. Who is responsible for identifying program income?
2. How program income is generated?
3. Record keeping procedures for recording the earning, receipt, and disposition of the program income for which the institution is accountable.
4. A management system that adequately identifies and reports program income for each government project.

### **Standards of Conduct**

NIH grants are subject to requirements intended to ensure that organizations are responsible in their handling of Federal awards and to minimize the opportunity for improper financial gain on the part of employees, consultants, members of governing bodies, and others who may be involved in grant-supported activities, and to limit the potential for research results to be tainted by possible financial or other gain. In addition, NIH grantees are expected to provide safe and healthful working conditions for their employees and foster work environments conducive to high-quality research.

Grantees must have written standards of conduct that establish safeguards to prevent employees, consultants, members of governing bodies, and others who may be involved in grant-supported activities from using their positions for purposes that are, or give the appearance of being motivated by a desire for private financial gain for themselves or others, such as those with whom they have family, business or other ties. Grantees are also required to comply with the requirements of 42 CFR Part 50, subpart F, pertaining to investigator's actual or potential financial conflicts of interest. See the NIH Grants Policy Statement, December 2003, page 44. Website: [http://grants2.nih.gov/grants/policy/nihgps\\_2003/NIHGPS\\_Part4.htm#\\_Toc54600064](http://grants2.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part4.htm#_Toc54600064). See Attachment #9 for sample policy.

### **Laboratory Notebooks**

We recommend that organizations develop and implement a written policy covering laboratory notebook procedures. While not subject to Federal requirements, laboratory notebooks are vitally important as evidence for intellectual property rights to secure adequate patent rights. On the rare occasions when the laboratory notebook must be produced, it is absolutely necessary that it be a record that is sufficiently complete that another scientist can understand and reproduce the work, and that there is a witness who can give corroborating testimony if needed.

### **SBIR/STTR Policy Regarding Indirect Costs**

See NIH Grants Policy Statement, December 2003, page 244. Website:

[http://grants2.nih.gov/grants/policy/nihgps\\_2003/NIHGPS\\_Part13.htm#\\_Toc54600298](http://grants2.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part13.htm#_Toc54600298)

Phase I Grants. If the applicant small business concern has currently effective negotiated indirect costs rates with a Federal agency, such rates should be used when calculating proposed indirect costs. (However, these rates must be adjusted for independent [self-sponsored] research and development expenses, which are not allowable by the Department of Health and Human Services. A full discussion of "Indirect Costs" is contained in the SBIR and the STTR solicitations.) *If the applicant small business concern does not have currently effective negotiated indirect costs rates with a Federal agency, the applicant organization may propose estimated indirect costs at a rate not to exceed actual or 40 percent of the total direct costs, whichever is less. However, applicant small business concerns are reminded that only actual indirect costs are to be charged to projects.* The Division of Financial Advisory Services, NIH, is the office responsible for negotiating indirect cost rate agreements with for-profit institutions, and they will not negotiate indirect cost rates for Phase I awardees.

**Phase II Grants.** If the applicant small business concern does not have currently effective negotiated indirect costs rates with a Federal agency, the applicant organization should propose estimated actual indirect costs. *If being considered for an award, the applicant small business concern would be asked to submit detailed documentation justifying the proposed rate if it exceeded 25 percent of the total direct costs. However, applicant organizations are reminded that only actual indirect costs are to be charged to projects.* If the proposed rate exceeds 25 percent of the total direct costs, the Division of Financial Advisory Services, NIH, is the office responsible for negotiating indirect cost rate agreements with for-profit institutions.

### **Research Involving Human Subjects and/or Live Vertebrate Animals**

If the application includes research involving human subjects in non-exempt categories under 45 CFR Part 46 and/or live vertebrate animals and the organization does not have approved assurance(s) of compliance with the Office for Human Research Protections (OHRP), or Office for Laboratory Animal Welfare (OLAW), NIH that covers the research, the Awarding Office cannot issue an award until the required assurance(s) are in place. The organization will be contacted by OLAW if the pending application is selected for funding. See NIH Grants Policy Statement, December 2003, pages 54 through 66. Website:

[http://grants2.nih.gov/grants/policy/nihgps\\_2003/NIHGPS\\_Part5.htm](http://grants2.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part5.htm)

The OHRP website (<http://www.hhs.gov/ohrp/>) has a simplified process for filing Institutional Assurances of Protection for Human Subjects with the OHRP. Assurances approved under this process will cover all of the institution's federally supported human subject research. Each legally separate institution will need its own Federal Wide Assurance (FWA). A continuing education program on the protection of human participants in research is now available online at <http://cme.cancer.gov/c01>. All key personnel as defined in the June 2, 2000 NIH Guide announcement (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html>) must complete education on the protection of human subjects, in accordance with NIH policy requirements. See also NIH Grants Policy Statement, December 2003, page 61. Website:

[http://grants.nih.gov/grants/policy/nihgps\\_2003/NIHGPS\\_Part5.htm#\\_Toc54600083](http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part5.htm#_Toc54600083)

### **Reports and Record Retention**

The final financial report, a progress report, and invention statement (see complete invention reporting information at [http://grants.nih.gov/grants/funding/sbir\\_sttr\\_invention\\_letter.htm](http://grants.nih.gov/grants/funding/sbir_sttr_invention_letter.htm)) must be prepared and submitted 90 days after the project period end date specified on the notice of grant award. NIH Grants Policy Statement, December 2003, page 139. Website:

[http://grants2.nih.gov/grants/policy/nihgps\\_2003/NIHGPS\\_Part8.htm#\\_Toc54600152](http://grants2.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part8.htm#_Toc54600152)

For equipment, records shall be maintained for three years beyond the date of final disposition. Equipment purchased with federal funds must be disposed of in accordance with 45 CFR Part 74.34(g). All invoices and records relating to procurement shall be retained for a minimum of three years from the date of submission of the final expenditure report or, for awards that are renewed annually, from the date of the submission of the annual financial report, in accordance with 45 CFR Part 74.53. NIH Grants Policy Statement, December 2003, page 133. Website:

[http://grants2.nih.gov/grants/policy/nihgps\\_2003/NIHGPS\\_Part8.htm#\\_Toc54600143](http://grants2.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part8.htm#_Toc54600143)

### **Audit requirement information in the NIH Grants Policy Statement:**

[http://grants2.nih.gov/grants/policy/nihgps\\_2003/NIHGPS\\_Part8.htm#\\_Toc54600144](http://grants2.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part8.htm#_Toc54600144)

[http://grants2.nih.gov/grants/policy/nihgps\\_2003/NIHGPS\\_Part7.htm#\\_Toc54600129](http://grants2.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part7.htm#_Toc54600129), and

<http://oamp.od.nih.gov/dfas/faqforprofitaudits.asp>