DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

Dear BUSINESS OFFICIAL:

The grant application referred to above is in the process of being administratively reviewed by the National Cancer Institute (NCI). If the pending application is funded, you are required to maintain records that reflect your organization's implementation of and compliance with the financial and business management requirements as listed in the enclosed "SBIR/STTR FINANCIAL/MANAGEMENT SYSTEMS REQUIREMENTS" information document. This requirement will be referenced in a term (condition) of award.

It is important for your 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), October 1998, 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 in the attachments to this letter. DO NOT SEND THIS INFORMATION TO NCI UNLESS SPECIFICALLY REQUESTED.

In addition, if the pending application is funded, a SBIR/STTR VERIFICATION STATEMENT must be received and accepted in this office before an award will be issued. You may furnish the information in a format of your choosing or by using the enclosed list.

If you have any questions, please call or email the assigned grants specialist working on your grant.

Leo F Buscher Jr

Leo F. Buscher Jr.
Chief Grants Management Officer
National Cancer Institute

SBIR/STTR FINANCIAL REQUIREMENTS
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ATTACHMENTS

NIH SMALL BUSINESS INNOVATION RESEARCH PROGRAM
SMALL BUSINESS CONCERN VERIFICATION STATEMENT

Grant Application Number: _____
Organization: _____
Project Director(s)/Principal Investigator(s) (PD(s)/PI(s):_____

The Small Business Innovation Research (SBIR) program legislation requires that the applicant small business concern (SBC) be eligible at the time of the award. As the responsible Federal staff for administering NIH grant funds, Grants Management Officials of the NIH Institutes and Centers (ICs) must verify eligibility prior to issuing a Notice of Grant Award. If the SBC is affiliated with any other organization (domestic or foreign), see www.sba.gov/size.

If an application is selected for funding under the SBIR program, no award will be issued until the National Cancer Institute (NCI) receives and accepts the following information, which may be provided in a format of your choosing or by completing a checklist as in the example below:

☐ 1 The above-named organization is a for-profit United States SBC that is at least 51% owned and controlled by one or more *individuals* who are citizens of, or permanent resident aliens in, the United States, or in the case of a publicly-owned business, at least 51% of its voting stock is owned by United States citizens or lawfully admitted permanent resident aliens.
or
The above-named organization is a for-profit business concern that is at least 51% owned and controlled by another (one) for-profit business concern that is at least 51% owned and controlled by one or more *individuals* who are citizens of, or permanent resident aliens in, the United States.

Complete the following part of (1) if relevant: If the above-named applicant organization has been determined by the Small Business Administration (SBA) to be "other than small" for a size standard of not more than 500 employees or for purposes of the SBIR program:

Have you been recertified by SBA? ☐ Yes ☐ No
If not recertified, have you requested a recertification by SBA for eligibility under the SBIR program? ☐ Yes ☐ No

☐ 2 The above-named organization is independently owned and operated, is not dominant in the field of operation in which it is proposing, has its principal place of business located in the United States, has, including its affiliates, 500 or fewer employees, is not involved in a merger/acquisition that is near complete, and meets the other regulatory requirements found in Title 13, Code of Federal Regulations (CFR), Part 121. (Note that the SBA considers "agreements to merge (including agreements in principle) to have present effect on the power to control a concern" [Section 121.103(d)(1) of 13 CFR 121]).

☐ 3 The *research space* occupied by the above-named organization is available to and under the control of the above-named organization *for the conduct of its portion of the proposed project*.

☐ 4 All research on the above-referenced grant will be *performed in its entirety* in the United States, unless otherwise approved by the Grants Management Officer prior to issuance of an award.

☐ 5 The above-named PD's/PI's *primary employment* is with the above-named organization and more than one-half of the above-named PD's/PI's time will be in the employ of the above-named organization at the time of award and for the duration of the project, unless otherwise approved by the Grants Management Officer prior to issuance of an award. For Multiple PD/PI projects, the Contact PD/PI meets the primary employment requirement.

☐ 6 It is understood that the Public Health Service will not support any *market research* under its SBIR program (see "Definitions," SBIR/STTR SF424 (R&R) Application Guide) or literature searches that will lead to a new or expanded statement of work, and that if an award is made, any such costs, if requested in the application, will be removed prior to award.

☐ 7 It is understood that if this project is funded, drawing NIH award funds from the HHS Payment Management System serves as certification that the above-named organization has in place written policies and procedures for financial and business management systems that comply with 45 CFR 74 and the NIH Grants Policy Statement (12/03) and will follow those policies and procedures.

My signature is verification that the statements checked ( ) above are true and complete. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

_____ _____
(Official Authorized to Sign for the Organization) (Date)

NIH SMALL BUSINESS TECHNOLOGY TRANSFER PROGRAM
SMALL BUSINESS CONCERN VERIFICATION STATEMENT

Grant Application Number: _____
Organization: _____
Project Director(s)/Principal Investigator(s) (PD(s)/PI(s):_____

The Small Business Technology Transfer (STTR) program legislation requires that the applicant small business concern (SBC) be eligible at the time of the award. As the responsible Federal staff for administering NIH grant funds, Grants Management Officials of the NIH Institutes and Centers (ICs) must verify eligibility prior to issuing a Notice of Grant Award. If the SBC is affiliated with any other organization (domestic or foreign), see www.sba.gov/size.

If an application is selected for funding under the STTR program, no award will be issued until the National Cancer Institute (NCI) receives and accepts the following information, which may be provided in a format of your choosing or by completing a checklist as in the example below:

☐ 1 The above-named organization is a for-profit United States SBC that is at least 51% owned and controlled by one or more *individuals* who are citizens of, or permanent resident aliens in, the United States, or in the case of a publicly-owned business, at least 51% of its voting stock is owned by United States citizens or lawfully admitted permanent resident aliens.

Complete the following part of (1) if relevant: If the above-named applicant organization has been determined by the Small Business Administration (SBA) to be "other than small" for a size standard of not more than 500 employees or for purposes of the SBIR program:

Have you been recertified by SBA? ☐ Yes ☐ No
If not recertified, have you requested a recertification by SBA for eligibility under the SBIR program? ☐ Yes ☐ No

☐ 2 The above-named organization is independently owned and operated, is not dominant in the field of operation in which it is proposing, has its principal place of business located in the United States, has, including its affiliates, 500 or fewer employees, is not involved in a merger/acquisition that is near complete, and meets the other regulatory requirements found in Title 13, Code of Federal Regulations (CFR), Part 121. (Note that the SBA considers "agreements to merge (including agreements in principle) to have present effect on the power to control a concern" [Section 121.103(d)(1) of 13 CFR 121]).

☐ 3 The *research space* occupied by the above-named organization is available to and under the control of the above-named organization *for the conduct of its portion of the proposed project.*

☐ 4 All research on the above-referenced grant will be *performed in its entirety* in the United States, unless otherwise approved by the Grants Management Officer prior to issuance of an award.

☐ 5 The above named PD(s)/PI(s) has (have) a formal appointment with or commitment to the above-named organization, which is characterized by an official relationship between the organization and the PD(s)/PI(s), whose effort on this project will be not less than 10% of his or her total professional effort. For Multiple PD/PI projects, each PD/PI must commit a minimum of 1.2 calendar months (10% effort) to the project.

☐ 6 It is understood that the Public Health Service will not support any *market research* under its STTR program (see "Definitions," SBIR/STTR SF424 (R&R) Application Guide) or literature searches that will lead to a new or expanded statement of work, and that if an award is made, any such costs, if requested in the application, will be removed prior to award.

☐ 7 In conducting the joint research and development proposed in this project, the above-named applicant SBC will conduct not less than 40% of the work and the single, "partnering" research institution named in the application will perform not less than 30% of the work.

☐ 8 It is understood that if this project is funded, drawing NIH award funds from the HHS Payment Management System serves as certification that the above-named organization has in place written policies and procedures for financial and business management systems that comply with 45 CFR 74 and the NIH Grants Policy Statement (12/03) and will follow those policies and procedures.

My signature is verification that the statements checked ( ) above are true and complete. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

_____ _____
(Official Authorized to Sign for the Organization) (Date)

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

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

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

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

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

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

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. 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. 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, 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
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. 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

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

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

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) 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

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

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_Part7.htm#_Toc54600129, and
http://oamp.od.nih.gov/dfas/faqforprofitaudits.asp

Attachment #1

Clarification of Audit Requirements of For-Profit Organizations Including SBIR/STTR

The Department of Health and Human Services (HHS) has specified requirements for non-federal audits of for-profit (commercial) organizations in HHS' Title 45, Code of Federal Regulations [CFR], Part 74.26, "Non-Federal Audits."

Per the regulations, a for-profit (commercial) organization is subject to audit requirements for a non-federal audit if, during its fiscal year, it **expended** $500,000 or more under HHS awards and at least one award is a HHS grant.

Title 45 CFR Part 74.26 essentially incorporates the thresholds and deadlines of Office of Management and Budget (OMB) Circular No. A-133, "Audits of States, Local

Governments and Non-Profit Organizations," but provides for-profit organizations with two options regarding the type of audit that will satisfy the audit requirements: either (1) a financial related audit (as defined in the Government Auditing Standards, GPO Stock #020-000-00-265-4) of all the HHS awards in accordance with Government Auditing Standards, or (2) an audit that meets the requirements contained in OMB Circular No. A-133.

The Government Auditing Standards document is available electronically at http://www.gao.gov/govaud/govaudhtml/index.html.

OMB Circular No. A-133 is found on the Internet at http://www.whitehouse.gov/omb/circulars/a133/a133.html.

Audits shall be completed and submitted to the following office within a period of time that is either (1) the earlier of 30 days after receipt of the auditor's report(s), or (2) nine months after the end of the audit period (that is, the organization's fiscal year): National External Audit Resources, HHS Office of Audit Services, Lucas Place, 323 West 8th Street, Room 514, Kansas City, MO 64105.

The HHS will be identifying organizations not meeting audit requirements. Failure to comply may jeopardize eligibility for receiving future HHS awards.

Chart of Accounts

ACCOUNT CODE	TITLE
Current Assets	
1000	Cash
1020	Accounts Receivable
1040	Inventory - Work in Progress
1060	Prepayments
Property, Plant, & Equipment	
1100	Equipment - Lab
1101	Accumulated Depreciation-Lab Equip
1110	Equipment - Office
1111	Accumulated Depreciation-Office Equip
1200	Leasehold Improvements
1201	Accumulated Amortization-Leasehold Improvement
Other Assets	
1800	Deposits
Current Liabilities	
2000	Current Note Payable
2010	Accounts Payable
2030	Accrued Wages and Payroll Taxes Withheld
Long Term Liabilities	
2100	Note Payable
Equity	
3000	Common Stock
3001	Retained Earnings
Revenue	
4000	Commercial Sales
4010	Grant Revenue
4020	Interest Income
Direct Program Costs	
5000	Direct Labor
5100	Consultants
5200	Equipment
5300	Materials and Supplies

5400 Travel
5500 Other/Misc
5600 Consortium/Contractual

Fringe Benefits

6010 Vacation
6015 Holidays
6020 Sick Leave
6025 Payroll Taxes
6030 401(k) Plan
6035 Group Insurance

Overhead

7000 Overhead Labor
7110 Amortization-Leasehold Improvements
7120 Depreciation-Lab Equipment
7130 Depreciation-Office Equipment
7140 Rent
7150 Utilities
7160 Telephone
7170 Equipment Rental
7180 Expendable Equipment
7190 Repairs & Maintenance
7200 General Lab Supplies
7210 Travel
7220 Consultants
7230 Waste Diposal
7240 Training

G&A

8000 G&A Labor
8010 Amortization-Leasehold Improvements
8015 Depreciation-Office Equipment
8020 Rent
8030 Utilities
8040 Telephone
8050 Equipment Rental
8060 Expendable Equipment
8070 Repairs & Maintenance

8080 Office Supplies
8090 Travel
8100 Consultants
8110 Legal & Accounting
8120 Liability Insurance
8130 Licenses
8140 Dues & Subscriptions
8150 Postage
8160 Recruitment/Relocation

8800 IR&D Labor

Unallowables

9000 Interest Expense
9010 Contributions
9015 Exhibits

Time and Effort Reporting for Commercial Organizations

Policy

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:

- Charged to direct projects
- Charged to indirect activities
- Included in the base to which indirect costs are allocated.

Internal controls

Timekeeping procedures and controls on labor charges are of utmost concern. Unlike other costs, labor is not supported by external documentation or physical evidence which provides independent checks and balances. It is critical that managers indoctrinate individual employees on their independent responsibility for accurately recording their time. Internal controls over labor charging should meet the following criteria:

- The responsibility for timekeeping and payroll accounting should be separated.

- Procedures must be clear and reasonable so there is no confusion regarding the rationale for the controls or misunderstanding as to what is and is not permissible.

- Maintenance of controls must continually be verified, and violations must promptly and effectively be acted upon to serve as a deterrent to prospective violations.

- Individual employees must constantly be made aware of controls that act as an effective deterrent against violations. This awareness can be accomplished by emphasizing the importance of accurate time and effort reporting in orientation sessions, periodic meetings and the posting of messages as reminders.

- Changes on timesheets to the number of hours recorded or the cost center identified should be made by the employee **and** must be initialed by the employee.

- The company policy must state that the nature of the work performed determines the proper distribution of time, not the availability of funding, type of contract/grant or other factors.

- The company policy should emphasize that complete and accurate time and effort reporting is an important part of an employee's job. Careless or improper reporting may lead to disciplinary actions under company policies as well as applicable Federal statutes.

Time and Effort Documentation Requirements and Responsibilities

Detailed instructions for time documentation should be established in written company procedures. A manual system would require handwritten pen and ink entries on a paper timesheet reflecting all the days in the pay period. An automated timekeeping system typically would use remote data entry for recording labor charging data and sending it directly to a central computer for processing. Supporting documentation for an automated system would normally consist of computer printouts showing data that appear on source documents, i.e., timesheets, in a manual system.

Employee Responsibilities

Whether a manual or automated time and effort reporting system is in place, the employee is personally responsible for:

- After the fact recording of hours (or fractions thereof) on a daily basis.
- Recording all hours worked and all hours absent. All hours should be recorded whether or not they are paid.
- Recording of hours on the timesheet in ink (manual system only).
- Recording the correct distribution of hours by project or indirect category. The nature of the work performed determines the proper distribution of time, not the availability of funding, type of contract/grant or other factors. To ensure accuracy, a listing of project numbers/indirect categories and their descriptions should be provided in writing to each employee.
- Any changes/corrections to timesheets should be made by the employee and must show what was initially recorded, i.e., no erasures or "white out" of entries. The employee also must initial any change(s).
- At the end of each pay period, the employee must sign the timesheet or electronically certify the labor distribution in an automated system.

Supervisor Responsibilities

- An authorized company official (e.g., supervisor) must cosign timesheets or electronically certify individual time and effort reporting at the end of each pay period.

- The supervisor is prohibited from completing an employee's timesheet or entering hours in an automated system unless the employee is absent for an extended time on some form of authorized leave.

Attachment #4

Time Sheet

Employee Name__

Employee Signature.

.Supervisor Signature.

MONTH:. YEAR:

DAY:	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15		TOTAL
	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	
PROJECT:																	
INDIRECT*																	
VACATION																	
HOLIDAY																	
SICK LEAVE																	
OTHER																	
TOTAL																	

EMPLOYEE INSTRUCTIONS: Time Sheet must be completed in ink and corrections should be initialed by employee. For each day of the month (column) enter the number of hours worked on each project (as well as IR&D) or individual indirect category. At the end of the reporting period, sum the number of hours in the "Total" column and enter on the last line in the column. Sign and date the time sheet, and give it to your supervisor.

•Record the number of hours by indirect category (tor example; overhead, G&A, Sales, Marketing etc.)

Sample Consultant Services Policy

Consultant Services Policy and Procedures:

The Corporation may utilize a number of consultants to help in highly specialized areas (e.g. Intellectual Property) or where it is not economical to hire a full-time person to fill a position for a short-term project. The use of consultants allows the Corporation to gain access to highly skilled professionals to assist in very specialized areas.

The process for determination of need and selection process is as follows:

Step	Description	Responsible
Consulting Request	Identification of the need for outside consulting services to be used. All requests are reviewed at weekly management meeting.	Anyone in the Corporation may submit a request
Approval of Consulting	Approve request for consultant services.	President/CEO
Selection of Consultant	Selection depends on area of specialty. For scientific/research, the Chief Science Officer will make the selection. The President/CEO selects all other consultants.	President/CEO Chief Science Officer
Rates and Contract	All consultants are required to sign a consultant agreement that describes the services to be performed, the rate of payment, and terms (e.g., confidentiality) All rates are approved by the President/CEO and basis determined by regional salary scales, consultant institutional rate, or other reasonable methods.	President/CEO
Payment	Consultants must submit an invoice for services prior to payment. Rate based consultant services (e.g. hourly or daily charge), the invoice must include the time report specifying date, time, and description of work. The President/CEO, prior to payment, must approve fixed fee consultant services after review of consultant report/work performed.	President/CEO

SAMPLE SAMPLE SAMPLE

Policies and Procedures for Procurement

Purpose: To establish standards and operating procedures for purchase of supplies and equipment.

General Policy: All procurement transactions shall be made in a manner to provide, to the maximum extent practical, open and free competition. The Company shall be alert to organizational conflicts of interest as well as noncompetitive practices among contractors that may eliminate competition or otherwise restrain trade.

Small purchases, less than $5,000, shall be subject to comparison among competitive suppliers to assure the most economical and practical procurement of goods and services. Large purchases may be subject to a bid or quote, where practical, to assure that the purchase meets Company requirements and specifications.

The type of procurement instrument (e.g., fixed price contracts, cost reimbursable contracts, purchase orders, incentive contracts) shall be appropriate for promoting the best interest of the program or project involved. Current inventories shall be screened to avoid duplicative purchases.

Whenever possible, procurement will be made from small businesses, minority-owned firms, and women's business enterprises. Identification of these organizations may be made with the assistance of the Small Business Administration and the Department of Commerce's Minority Business Development Agency.

Contracts shall be made only with responsible contractors who possess the potential ability to perform successfully under the terms and conditions of the proposed procurement. Elements to be considered may include, but are not limited to, record of past performance, financial and technical resources or accessibility to other necessary resources, and eligibility to receive federal funds.

Procedures

1. Authority: All chemicals and other laboratory supplies shall be ordered by the laboratory manager or principal investigator. Purchases in excess of $5,000 must be preapproved by the President or other authorized business official for the Company. Review of the existing stock, supplies or equipment shall be made prior to submitting purchase orders to avoid duplication.

2. Requisition for order: All orders are to be documented on numbered purchase orders with the following information included:
    a. Vendor
    b. Ship to address
    c. To be billed address
    d. Date ordered
    e. Project code
    f. Items ordered
    g. Description
    h. Price, if available

SAMPLE SAMPLE SAMPLE

3. Place the order: Place the order by mail, fax or phone as necessary for prompt delivery of required chemicals and supplies. Obtain the name of the individual at the vendor site who is taking the order over the phone.

4. Receiving the order: The receiving person must verify:

a. The quantity actually received agrees with the packing slip and the purchase order b. The receiving person must initial and date the packing slip and the purchase order - $_{Y}$c. Forward a copy of the purchase order and the verified packing slip to the bookkeeper for processing invoice payment

d. Equipment shall be tagged with an identification number and entered into the inventory recordbook. Equipment purchased with federal funds shall be further identified with the project number on the ID tag. The inventory records for —- - equipment includes all of the following:

(1) Description of the equipment
(2) Manufacturer's serial number, model number, Federal stock number and National stock number (if applicable), and identification number
(3) Source of equipment (award number or project number)
(4) Acquisition date
(5) Location and condition of the equipment (updated annually for inventory)
(6) Unit acquisition cost
(7) Ultimate disposition of equipment, including date of disposal, and sales price. For equipment purchased with federal funds, the method used to determine current fair market value where the Company compensates the federal government.

5. Paving the invoice:

a. The packing slip and the purchase order must be reconciled with the invoice received direct from the vendor
b. Payment by check shall be made on a timely basis to avoid penalties or late fees
c. Code the disbursement payment for project accounting
d. Cross reference the check number and date with the invoice paid
e. Present completed check with supporting document to President for signature
..... ^ pjj$_{e\ tne\ mvQ}$j$_{ce\ an(}$j $_{a}$n $_{re}$i$_{a}$ted documents together by vendor

6. Review of procurement by Board of Directors: Quarterly, or more frequently if determined necessary, the Board of Directors shall review the paid invoices for the quarterly period to provide a review of the procedures and expenditures.

7. Purchase order format: Attached is a purchase order form to be used for supplies procurement.

Purchase Order Request Form

Req. No. _____ Purchase Order No. _____

Account No. _____ Account Name _____

Professor's Name _____ Signature _____

Your Name _____ Your Email _____ Your Phone Number _____

Date _____

Special Instructions:

Item No.	Description	Quantity	Unit (each, pkg, case)	Per-Unit Price	Line Item Total Price

☐ In Stock ☐ Lead Time _____ **Total Price** _____

Shipping Preference ☐ Ground ☐ Express

Complete Name of Vendor: _____ Name of Contact: _____

Address of Vendor: _____ Contact's phone number: _____

_____ Contact's fax number: _____

Please attach any web printout or email or faxed quotation received from vendor.

EXPENSE REPORT ATTACHMENT #7a

Name:	Report Period:	Purpose:
Event:	Place:	

For SBIR Travel Only

Date	City and State	Lodging	Lodging Per Diem	Lodging Excess	Meal Per Diem	Entertainment & Business Meals (Itemized Below)	Airfare/Milage	Car Rental/Taxi	Parking/Tolls	Phone/Fax	Miscellaneous (Itemized Below)	Daily Total
TOTALS:												
											Less Advance	
											Total	

(Government approved per diem rates for the tavel city- http://www.gsa.gov)

ENTERTAINMENT AND BUSINESS MEALS

Date	Name, Company, Title of Person(s) Entertained	Business Discussed	Time and Place	Amount	% Allocated to Business

MISCELLANEOUS EXPENSES

Date	Item	Amount

I hereby certify that the above is a true and accurate account of my expenses in connection with the stated company business.

Signature: Date:

Approved: Date:

Attachment #8

SAMPLE **SAMPLE** **SAMPLE**

POLICY AND PROCEDURES RELATED TO CONSORTIUM/CONTRACTUAL AGREEMENTS

1. Background

A consortium grant is defined as the following. It is a grant to one institution in support of a research project in which any programmatic activity is carried out through a collaborative arrangement between or among the grantee institution and one or more other institutions or organizations which are separate legal entities, administratively independent of the grantee. The involvement of the non-grantee (collaborating) institution is that of actually performing a portion of the programmatic activity as opposed to simply providing a routine service to the grantee such as equipment fabrication or repair, data processing, or performing routine analytical testing services.

When in-house expertise required for a project does not exist, the Company may have the need to enter into a consortium agreement or other contractual relationship(s) with another entity or entities in regard to scientific/research matters or otherwise. The policy and process for identifying need for such relationships (and the negotiation and execution thereof) are as follows:

2. Identification of Need and Responsible Officer

Responsibility of selection of a consortium partner depends on the area of specialty involved. For scientific/research activities, the Vice President of Research shall identify possible entities and make the selection based on the qualifications of such entity. The President shall be responsible for negotiating consortium agreements in all other matters.

3. Terms and Conditions

All consortium agreements shall be in writing, and shall, at a minimum, include the following terms and conditions:

a. Describe the activity to be performed by the respective parties
b. Set the start and finish dates, including milestones as applicable
c. Amount of payment due and related schedule for submission of payment voucher
d. Require that the consortium certifies compliance with all federal regulations, policies, assurances and requirements pertinent to the project
e. Terms from the awarding agency that are pertinent to the consortium
f. Due date for progress report

4. Legal Counsel

In the event that legal counsel is required to negotiate any applicable consortium agreement terms, approval of the President is required before the Vice President of Research or any other Officer engages the assistance of counsel.

5. Review and Payment

The principal investigator at the Company shall be responsible for reviewing the progress reports and the detailed payment voucher from the consortium. After review and approval of the report and voucher, the documents shall be sent to the bookkeeper for payment. Any discrepancies or problems identified by the principal investigator shall be immediately reported to the President.

6. Final Authority

All consortium agreements or other similar contracts must be signed by the President or the designated company official in order to commit the Company and the contract must be countersigned by an authorized business official of the selected entity.

SAMPLE Attachment #9

In addition, the organization must also have written standards of conduct that comply with the requirements set forth in the NIH Grants Policy Statement, December 2003

POLICY FOR MANAGING CONFLICTS OF SIGNIFICANT FINANCIAL INTERESTS

I. INTRODUCTION

A. General Policy

The principles articulated herein are intended to provide guidance in the management of formal relationships between employees of Insert Company Name ("Company") and their external constituencies in order to ensure that the design, conduct, and reporting of sponsored research will not be biased by any conflicting financial interests. Under the Public Health Service (PHS) and National Science Foundation (NSF) final rules on Objectivity in Research (Federal Register, July 11, 1995), each investigator is required to disclose a listing of his/her significant financial interests, as well as those of his/her spouse and dependent children, that would reasonably appear to be affected by the research purposed for funding by the PHS or the NSF. If, after review of these disclosures, it is determined that the reported financial interests could directly and significantly affect the design, conduct, or reporting of the research, the Company will report the existence of such conflicting interests to the sponsor and act to protect the resulting research from bias owing to the conflict of interest. This policy statement is intended to satisfy current Federal rules for disclosure with regard to projects funded by the PHS or the NSF as well as State of California statutes involving conflict of interest situations.

B. SCOPE

This policy and the associated procedures are applicable immediately to all sponsored program activity at _____ carried out by Company employees, consultants, scientists, trainees, technicians and other agents or research collaborators ("Company employees"). The policy and the associated procedures are derived from the final rules on *Objectivity in Research* promulgated by the PHS and the NSF that were published in the *Federal Register* of July 11, 1995. These procedures will be followed whenever _____ or its employees submit a request for funding from any external agency, whether it is the PHS, the NSF or another Federal agency.

C. RESEARCH AND THE MISSION STATEMENT

The Mission Statement for _____ states:

The Company's Mission:

Such company research is facilitated and/or made possible through external funding from private as well as public sources. It is the Company's responsibility to assure the integrity of all aspects of such sponsored research while, simultaneously, taking care not to discourage the development of external funding opportunities. The purpose of this document is to identify situations where potential conflicts of significant financial interest are likely to arise and to establish a process whereby such conflicts are either avoided or at least managed equitably to the satisfaction of all concerned parties.

D. MANAGING CONFLICTS OF SIGNIFICANT FINANCIAL INTEREST

This document articulates Company policy on the management or elimination of conflicts of significant financial interest between outside constituencies and the associated funded activities carried out by Company. While this policy focuses upon avoiding, or at least managing, conflicts of significant financial interest, its primary purpose is to promote compliance with the standards of Objectivity in Research.

II. DEFINITIONS

A. *Conflict of Significant Financial Interest* is considered to occur whenever a Company employee, or a family member of the Company employee, has an existing or potential financial or other material interest that impairs, or appears to impair, the Company employee's independence and objectivity in the discharge of his/her responsibilities to and/or for the Company; or, alternatively, conflict of significant financial interest is considered to occur whenever a Company employee receives financial or other material benefit through inappropriate use of knowledge or information confidential to the Company.

B. *Company Employee* is any individual employed on a full- or part-time basis by _____ and is receiving, or will receive, compensation for such employment. (Includes Consultants, Agents and Research Collaborators of Company).

C. *Investigator* is the principal investigator, co-principal investigators, or any other Company employee responsible for the design, conduct, or reporting of externally funded scientific research activities.

D. *Family member* includes the Company employee's spouse and children or other adults who qualify as dependents under the Internal Revenue Code definitions.

E. *Project* implies any externally funded activity such as basic, applied, or developmental research, or other activity conducted by Company employees on behalf of the Company.

F. *Significant F inancial Interest* is any item of monetary value including, but not limited to: 1) salary or other payments for services rendered such as consulting fees; 2) equity interests such as stocks, stock options, or other ownership interest; and 3) intellectual property rights such as patents copyrights, and royalties from such intellectual property rights. *Significant Financial Interest* does not include: 1) Company remuneration such as salary or royalties; 2) consulting fees from service on advisory committees or review panels for public or nonprofit entities; or 3) financial interest in business enterprises or entities where the value of such interests would not be anticipated to exceed $10,000 per annum or represent more than a five per cent (5%) ownership interest. The value of such equity interests is to be determined on the basis of public prices or other reasonable measures of fair market value.

G. *Negative Finding* means a determination has been made that no conflict of significant financial interest exists.

H. *Positive Finding* means a determination has been made that a conflict of significant financial interest does exist and, therefore, appropriate administrative action will be required as given under III.D. below.

III. POLICY STATEMENT

A. MANDATORY DISCLOSURE OF SIGNIFICANT FINANCIAL INTERESTS

In accord with relevant Federal and State of California regulations, the Company is required to manage, eliminate, or reduce any potential conflicts of significant financial interests that may be inherent in the personal financial interest of an investigator. Company, therefore, requires investigators to disclose to the Company, any significant financial interest, including those of his/her family members, which would reasonably appear to be affected by the project being funded by external government agencies. Investigators are required to provide updated disclosure information during the time period in which the proposal is pending, annually during the time period of an award, or whenever new significant financial interests are obtained by the investigator.

B. IDENTIFICATION OF CONFLICTS OF SIGNIFICANT FINANCIAL INTEREST

In conjunction with the administrative review of applications for grants, the Director of Research, in conjunction with the Manager of Human Resources and the Manager of Corporate Legal Services will review each Financial Disclosure submitted and shall make the determination of whether or not a conflict of significant financial interest exists. If the Director of Research, Manager of Human Resources and Manager of Corporate Legal Services determines that no conflict of significant financial interest exists, the resulting negative finding will be filed in the Company's Legal and Human Resource files. For negative findings no further review is required.

C. APPEAL OF POSITIVE FINDINGS

Investigators may appeal a resulting positive finding to the President for a review of the conflict of significant financial interest determination reached by the Director of Research, Manager of Human Resources and Manager of Corporate Legal Services. The review of an appealed positive finding must be completed prior to the expenditure of any funds under an award. In reviewing positive findings, the President will be guided by the following principles: 1) Assure adherence to all relevant Company policies; 2) Give full considerations to the nature and extent of the financial interests in the relationship of the investigator, and/or the investigator's family members, with the external constituencies; 3) Give special consideration to the terms and conditions of sponsored project agreements that mitigate or complicate the given situation; and 4) Consult fully with the investigator and obtain additional information from the investigator, as deemed appropriate to the management of the apparent conflict of significant financial interest.

D. MANAGING POSITIVE FINDINGS OF SIGNIFICANT FINANCIAL INTEREST

Following the determination of a positive finding, or upon receipt of the review by the President, The Director of Research, Manager of Human Resources and Manager of Legal shall make a final determination involving one of the administrative actions: 1) Accepting the sponsored project award; 2) Not accepting the sponsored project award; or 3) Accepting the sponsored project award subject to suitable modifications in the award documentation or in the investigator’s, or his/her family's, affiliation with the external constituencies involved. Reasonable modifications under option 3) above might include one or more of the following actions; 1) Requiring that public disclosure of the identified financial interests be made; 2) Requiring that the data and research results be reviewed by independent reviewers identified by the President and the investigator; 3) Requiring that the research plan be modified; 4) Requiring that the investigator be disqualified from participation in a portion of the research; 5) Requiring that the investigator and/or her/his family member(s) divest certain significant financial interests related to the positive finding; or 6) Requiring that the investigator and/or his/her family members(s) sever relationships that create the conflict of significant financial interest.

E. COMPLIANCE

If an investigator who is required under this policy to file a conflict of significant financial interest disclosure fails to do so or fails to disclosure a significant financial interest on the disclosure form, the investigator may be subject to company and legal procedures. If an unreported significant financial interest involves a research project administered by the Company, appropriate administrative action required by the funding agency will also be taken. _____will promptly notify the funding agency if it is determined that the company is unable to manage satisfactorily any conflict of significant financial interest. Intentional disregard for this policy, including non-adherence to the agreed upon management plan, shall constitute serious misconduct and may be the basis for further administrative or legal inquiry.

SAMPLE FORM Attachment #9

DISCLOSURE OF
SIGNIFICANT FINANCIAL INTERESTS FORM

Name: _____ Department: _____

Title: _____

Grant Proposal Title: _____

Intended Government Funding Agency: _____

Name of Constituent Organization/Institution in which you claim a Significant Financial Interest:

_____
Name

_____
Address

_____
City State Zip

Describe in detail the nature of your financial interest or role in the Constituent Organization or institution with respect to the following:

1. Describe your significant financial interest in the organization (other than _____) that is directly related to your research interest (or would be affected by your research) or directly relates to a business decision you are participating in.

_____
_____
_____

"*Significant Financial Interest*" means anything of monetary value, including but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equality interest (e.g. stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights).
The term does not include:
(1) salary, royalties, or other remuneration from the applicant institution;

(2) any ownership interest in the institution, if the institution is an applicant under the SBIR Program;
(3) income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;
(4) income from service on advisory committees or review panels for public or nonprofit entities;
(5) an equality interest that when aggregated for the Investigator and the Investigator's spouse and dependent children, meets both of the following tests: does not exceed $10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and does not represent more than five percent ownership interest in any single entity;
(6) salary, royalties or other payments that when aggregated for the investigator and the investigator's spouse and dependent children over the next twelve months, are not reasonable expected to exceed $10,000.

2. Describe your involvement or financial interest that is, or could be perceived to be, in conflict with the discharge or your duties at:

_____
_____
_____

SAMPLE

Screening form for Identifying Conflicts of Significant Financial Interests

Name: _____ Department: _____
(Investigator)
Title/Status: _____ Other Affiliate or Status: _____
(Employee, Consultant)

Grant Proposal Title: _____

Intended Government Funding Agency: _____

1. Do you have a *significant financial interest* in a commercial organization (other than _____) that is directly related to your research interest (or would be affected by your research) or directly relates to a business decision you are participating in?

For this purpose "Significant Financial Interest" means an interest which annually exceeds $10,000 in value (such as salary, consulting fees, fees for seminars, lectures, royalties, or intellectual property rights) or an ownership interest or Stock Option(s) in the organization which exceeds 5% when aggregated with the interests of your spouse and dependent children. (Excluding any remuneration from _____)

2. Do you have some involvement or financial interest that is, or could be perceived to be, in conflict with the discharge of your duties at _____? □ Yes □ No

3. Do you have a consulting or other financial relationship with a non-governmental external sponsor/donor of your research? □ Yes □ No

4. Do you have a managerial role in or an opportunity for personal gain through a *significant financial interest* in a company in a field of your research or a company that does business with _____? □ Yes □ No

5. Do you or any member of your family have any relationships, commitments, or activities that might, in your good faith judgment, present or appear to present a conflict of interest with your research activities? □ Yes □ No

6. Do you currently have, or will this proposal lead to the award of, external funding for research in a subject area in which you also have a *significant financial interest* in any external activity such as a managerial or ownership role in a company or an opportunity to receive *significant financial interest*? □ Yes □ No

If you answer yes to any of the above questions, you will be asked to disclose in further detail any Significant Financial Interest. Italicized phrases are defined in the Policy For Managing Conflicts of Significant Financial Interest at _____.

Affirmation: In submitting this form, I affirm that the above information is true and accurate and, further, that I accept responsibility for being familiar with the Policy for Managing Conflicts of significant Financial Interest at _____.

Signature: _____ Date: _____

Approved: __ Disapproved __ Signature:_____ Date: _____

Lab notebook

From Wikipedia, the free encyclopedia
(Redirected from Laboratory notebook)

A **lab notebook** is a primary record of research. Researchers use a lab notebook to document their hypotheses, experiments and initial analysis or interpretation of these experiments. The notebook serves as an organizational tool, a memory aid, and can also have a role in protecting any intellectual property that comes from the research.

The guidelines for lab notebooks vary widely between institution and between individual labs, but some guidelines are fairly common. The lab notebook is usually written in as the experiments progress, rather than a later date. Many say that lab notebook should be thought of as a diary of activities that are described in sufficient detail to allow another scientist to follow the same steps.

To ensure that data cannot be easily altered, notebooks with permanently bound pages are often recommended. Researchers are often encouraged to write only with unerasable pen, to sign and date each page, and to have their notebooks inspected periodically by another scientist who can read and understand it. All of these guidelines can be useful in proving exactly when a discovery was made, in the case of a patent dispute.

Several companies now offer electronic lab notebooks. This format has gained some popularity, especially in large pharmaceutical companies, which have large numbers of researchers and great need to document their experiments.

See also

- Electronic lab notebook
- Inventor's notebook
- Composition book

Retrieved from "http://en.wikipedia.org/wiki/Lab_notebook"

Categories: Articles to be expanded since January 2007 | All articles to be expanded | Articles lacking sources from October 2007 | All articles lacking sources | Scientific documents | Research | Notebooks

Electronic lab notebook

From Wikipedia, the free encyclopedia

An **electronic lab notebook** (also known as electronic laboratory notebook, or ELN) is a software program designed to replace paper laboratory notebooks. Lab notebooks in general are used by scientists and technicians to document research, experiments and procedures performed in a laboratory. A lab notebook is often maintained to be a legal document and may be used in a court of law as evidence. Similar to an inventor's notebook, the lab notebook is also often referred to in patent prosecution and intellectual property litigation.

Electronic lab notebooks are a fairly new technology and offer many benefits to the user as well as organizations. For example electronic lab notebooks are easier to search upon, support collaboration amongst many users, and can be made more secure than their paper counterparts.

ELNs can be divided into two categories:

- "Specific ELNs" contain features designed to work with specific applications, scientific instrumentation or data types.
- "Cross-disciplinary ELNs" or "Generic ELNs" are designed to support access to all data and information that needs to be recorded in a lab notebook.

The laboratory accreditation criteria found in the ISO 17025 standard needs to be considered for the protection and computer backup of electronic records. These criteria can be found specifically in clause 4.13.1.4 of the standard.

External links

- Tutorial: Electronic Laboratory Notebook Systems (Genetic Engineering News) (http://www.genengnews.com/articles/chitem.aspx?aid=1075)
- ELNS Worthy of note (Scientific Computing World) (http://www.scientific-computing.com/scwjunjul06elns.html)
- The State of the ELN Market (Scientific Computing World) (http://www.scientific-computing.com/features/feature.php?feature_id=50)
- ISO/IEC 17025 Resource Center (http://www.isoiec17025.com)

Retrieved from "http://en.wikipedia.org/wiki/Electronic_lab_notebook"

Categories: Articles to be expanded since January 2007 | All articles to be expanded | Intellectual property law | Research

Electronic Laboratory Notebook Systems

Cross Disciplinary ELNs Help Maximize R&D Efficiency

The breakdown of traditional R&D silos in biotechnology and pharmaceutical companies has accelerated the drug discovery and development process, but it has also led to an increased need for robust communications and data-sharing mechanisms. Paper laboratory notebooks, the simplest and most commonly used method for recording scientific data, are no longer meeting the needs of scientists in the electronic-data and/or intellectual-property (IP) driven biopharmaceutical industry.

The limitations of paper notebooks, coupled with the increased acceptance of electronic records by the FDA, has led to the development of innovative software programs that allow scientists to create electronic records that efficiently capture and store data and supporting information.

Known as electronic laboratory notebooks, or ELNs, these systems offer secure version control and audit trails to capture the flow of the scientific process, promote collaboration among scientists, and help protect intellectual property assets.

Limitations of Paper Notebooks

Paper laboratory notebooks present innumerable challenges to the process of drug discovery and development, the most critical of these being the inability to efficiently locate relevant data for cross-departmental review or use, the potential loss of data, and poor or inconsistent security. Data searches require manual examination of handwritten entries and their supporting computer outputs that are printed and applied with tape.

It is estimated that in labs that employ paper notebooks, approximately 2030% of a scientist's time is spent managing notebook entries. Much of that time can be attributed to the writing and re-writing of similar protocols.

Yet despite the shortcomings of paper notebooks, ELNs historically couldn't be widely adopted for drug discovery and development purposes because they were primarily designed to meet the needs of chemists, were unable to integrate with legacy IT systems, and were not compliant with FDA standards for electronic records management. With a widening array of electronic record keeping functions designed to meet the needs of both biologists and chemists, however, ELNs are poised to supplant traditional paper systems in both academic and industrial laboratories.

Enterprise-Wide, Cross-Disciplinary Electronic Laboratory Notebook Solutions

Classified according to how specifically their capabilities cater to a particular group of researchers, ELNs can be divided into two categories. "Specific ELNs" contain features designed to work with specific applications, scientific instrumentation or data types. "Cross-disciplinary ELNs" are designed to support access to all data and information that needs to be recorded in a lab notebook.

An example of a cross-disciplinary electronic laboratory notebook is the Infotrieve (www.infotrieve.com) ELN, a system that can be deployed at large or small organizations to securely store data and protocols, protect intellectual property, enhance security, and facilitate collaboration. It uses industry standards for file types, recording features, formatting, storage, and architecture. It can be adopted across many departments at an organization and meet the diverse needs of researchers. It also provides flexibility to supplement or replace existing discipline-specific toolsets if alternative versions are desired, whether or not they are foreseen at the point in time at which the ELN is initially deployed.

Specifically, Infotrieve's ELN employs industry-standard technology, Oracle databases and the BEA WebLogic application server, and supports a variety of operating systems and hardware platforms. Cross-disciplinary features allow scientists to search against any data entered into the system. Searches can be conducted using several different parameters, including project or experiment title, text within the experiment, the name of the scientist responsible for the experiment, or user-defined parameters.

The ELN is designed to handle data from multiple experiment types, from high throughput data to other nonstandardized forms of entry, and it allows users to import data from many sources and disciplines. The client architecture is based on the Windows platform, so the user interface is familiar and experimental data may be entered into an ELN entry using drag-and-drop capabilities.

Improving Intellectual Property Protection and Data Security

Intellectual property is an important asset for any drug discovery and development company, large or small. ELNs support an organization's ability to protect its IP over time and through occurrences of personnel turnover. ELNs also enable organizations to package their IP for future mergers and acquisitions.

The new breed of electronic laboratory notebooks provides key security features that make them far more secure than paper notebooks. These include electronic signature and witnessing capabilities as well as password-protected logins that ensure only authorized personnel will access experimental results and analysis. The ELN also offers a permissions scheme, strict version control, and detailed audit trails that record access and changes to data.

The ELN complies with the FDA's 21 CFR Part 11 and 21 CFR Part 820 guidelines with respect to digital signatures, electronic-records management, and software quality systems management. In using standard PDF format for data storage, export, and printing, the ELN also complies with the FDA's requirement that electronic copies be readily available for inspection.

Creating Experimental Efficiencies

To increase the efficiency of experimental record keeping, ELNs enable data to be dragged-and-dropped into an experimental entry, one-click entry cloning that duplicates experiments, and templates that provide consistency among project entries.

The search capabilities of the ELN can also increase collaboration. Scientists can search the ELN network for data pertinent to their own experiments rather than manually tracking down collaborators for the information they need.

Improving drug discovery timelines, maximizing R&D efficiencies, and finding and advancing the most promising lead candidates require cross collaboration among scientists in different disciplines. As competitive and investor pressure to accelerate drug discovery and development continues to increase, paper record-keeping systems will continue to give way to electronic laboratory notebook systems, such as Infotrieve's ELN, that enable efficient data storage and enterprise-wide communication.

- Email

NIH SBIR/STTR Internet Guide

SBIR/STTR Sites of Interest

This is a list of useful URL web site addresses to the SBIR/STTR program. The sites provide pertinent information on policies, procedures, and issues, as they pertain to the SBIR/STTR program. Please use this helpful information as a source of reference on issues concerning the Small Business funding opportunities.

Advice and Information on SBIR and STTR

http://www.nih.gov
http://grants1.nih.gov/grants/guide/index.html
http://grants1.nih.gov/grants/funding/sbir.htm
http://grants1.nih.gov/grants/funding/sbir_policy.htm
http://www.nih.gov/news/
http://www.business.gov/
http://grants1.nih.gov/grants/oer.htm

Applications and Forms

- **SF 424 R&R SBIR and STTR Competing Applications**
  http://grants.nih.gov/grants/funding/424/index.htm
- **PHS 2590 Noncompeting - Progress Report for a Public Health Service Grant**
  http://grants.nih.gov/grants/funding/2590/2590.htm

OMB-Prescribed Grants Management Standard Forms

http://www.whitehouse.gov/omb/grants/grants_forms.html

- SF-269, Financial Status Report (Long Form)
- SF-269A, Financial Status Report (Short Form)
- SF-270, Request for Advance or Reimbursement
- SF-272, Federal Cash Transactions Report
- SF-272A, Federal Cash Transactions Report
- SF-LLL, Disclosure of Lobbying Activities -- as revised in 1996

Audit

http://grants1.nih.gov/grants/funding/sbir.htm
http://www.whitehouse.gov/omb/circulars/
http://www.access.gpo.gov/nara/cfr/waisidx_01/45cfr74_01.html (See Section 74.26)
http://www.gao.gov/govaud/ybk01.htm
http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part8.htm#_Toc54600144
http://oamp.od.nih.gov/dfas/faqforprofitaudits.asp

Biohazards (Health and Safety Guidelines)

http://grants2.nih.gov/grants/guide/notice-files/not95-209.html

Conflict of Interest

http://grants.nih.gov/grants/policy/coi/index.htm

http://grants1.nih.gov/grants/guide/notice-files/not95-179.html
http://grants1.nih.gov/grants/policy/coifaq.htm

Consortium
http://grants2.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part12.htm#_Toc54600251

Consultant
http://grants2.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part6.htm

Costs
http://grants2.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part6.htm

Division of Payment Management
http://www.dpm.psc.gov
http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part5.htm#_Toc54600110

Equipment
http://www.access.gpo.gov/nara/cfr/waisidx_01/45cfr74_01.html (See Section 74.34)

Expanded Authority/NIH Prior Approval
http://grants2.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part7.htm

Federal Acquisition Regulation (FAR – Cost principles for commercial organizations)
http://www.arnet.gov/far/

Federal Financial and Business Management Systems
http://www.niddk.nih.gov/fund/crfo/ffbms/

Financial Reporting Requirement
http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part8.htm#_Toc54600142

HHS CFR Title 45, Part 74
http://www.access.gpo.gov/nara/cfr/waisidx_01/45cfr74_01.html
http://www.hhs.gov/grantsnet/adminis/fedreg45.htm

Indirect Costs
http://www.arnet.gov/far/
http://oamp.od.nih.gov/dfas/rates.asp

Intellectual Property
http://grants1.nih.gov/grants/intell-property.htm

Invention Reporting
https://s-edison.info.nih.gov/iEdison
https://s-edison.info.nih.gov/iEdison/timeline.jsp

Misconduct in Science
http://ori.dhhs.gov/

NIH Welcome Wagon Memorandum
http://grants1.nih.gov/grants/funding/welcomewagon.htm

Other Business Sites of Interest
http://www.sbaonline.sba.gov/
http://www.sba.gov/SBIR/
http://sbirworld.com/

OLAW (Animals in Research)
http://grants1.nih.gov/grants/olaw/olaw.htm
http://grants1.nih.gov/grants/olaw/olawaddr.htm

OHRP (Human Subjects)
http://www.hhs.gov/ohrp

NIH Policy Statement
http://grants2.nih.gov/grants/policy/nihgps_2003

NIH Roadmap to Starting a Small Business
http://oamp.od.nih.gov/ContractToolBox/Roadmap_StartBusiness/TrainingManualOnline.pdf

SNAP – Streamline Noncompeting Application Process
http://grants1.nih.gov/grants/forms.htm
http://grants1.nih.gov/grants/guide/notice-files/not99-127.html

Time and Effort Reporting Requirements
http://ocm.od.nih.gov/dfas/forprofittime&effort.html

Travel
http://www.gsa.gov/Portal/gsa/ep/channelView.do?pageTypeId=8203&channelPage=/ep/channel/gsaOverview.jsp&channelId=-13224