Penn’s Standard Industrial Clinical Trial Agreement has been Revised

Based on a review process involving faculty, the Vice Provost for Research, the Office of General Counsel, and the Office of Human Research, ORS has extensively revised The University of Pennsylvania’s standard industrial clinical trial agreement. This agreement is now available on the ORS website at http://www.upenn.edu/researchservices/pdfs/clintrl.pdf.

Principal Investigators and their staff are urged to send this agreement to potential Sponsors as soon as a clinical trial agreement is anticipated. If Sponsors agree to use this template without change, contract negotiations would not be necessary.

Any questions about this agreement or clinical trial agreement negotiations should be directed to Donald Deyo, Esq., Senior Associate Director, Corporate Contracts (deyo@pobox.upenn.edu).

NCI Issues a Reminder Regarding Any Applications Requesting $500,000 or More in Direct Costs

On September 27th, the National Cancer Institute issued a clarification which supplements the general NIH policy on this subject (published October 16, 2001) (grants.nih.gov/grants/guide/notice-files/NOT-OD-02-004.html).

The notice emphasized the requirement that applicants who plan to submit applications of $500,000 or larger direct costs must contact the National Cancer Institute Referral Office to seek approval at least 6 weeks before the application is submitted. All grant applications utilizing mechanisms, including but not limited to P01, P30, R01, R21/R33, and U10, where direct costs equal or exceed $500,000 are covered by this notice except for applications in response to a specific Request For Applications and Small Business Innovation Research Grants. This requirement covers new, competing continuations, supplements, and all amended applications. The information is specific for each receipt date and will not be carried over from one round to another. If an applicant is delayed and cannot meet the planned receipt date, a new request will be required for the next receipt date.

To facilitate and maintain a record of these actions, all communication regarding a request to exceed the $500,000 must be directed to the Referral Office of the NCI at the address below. A copy should be sent to the appropriate program director if known.

NCI Referral Office
National Cancer Institute
Division of Extramural Activities
6116 Executive Boulevard, room 8041, MSC 8329
Bethesda, MD 20892-8329

To view this notice in its entirety, please go to grants1.nih.gov/grants/guide/notice-files/NOT-CA-02-029.html.
BEN Will No Longer Allow Charges to Select Object Codes

Charges against select object codes will no longer be allowed in BEN on grant funds:

Effective October 1, BEN has been updated to no longer allow charges against certain object codes as specified below on any grant (5XXXXX) fund. These object codes should never have been used for charges on grant funds. This change is being made to avoid future errors. Please note that if a charge has already been made to one of these object codes on a grant fund, future charges will be allowed so that the situation can be adjusted as appropriate.

Also, please note that the Treasurer’s office will no longer be setting up Petty Cash funds against Grant Funds/5XXXXX funds.

Effective October 1, the following object codes WILL NOT BE allowed:

1200 - 1219
1240 - 1799
4820, 4825, 4920
5238, 5268, 5290, 5291, 5336

In addition, please note that 5046 should not be used for grant/5XXXXX funds. If you have any concerns regarding these changes, please contact Kerry Peluso, Director of Post Award Financial Administration at 3-6705 or pelusok@pobox.upenn.edu.

Some Tips on Completing Final Invention and Relinquishing Statements

Below are some tips to help expedite the processes required to ensure proper processing and timely release of these documents.

1. **Final Invention Statement:**
   As part of the final closeout of grant awards, most sponsors require disclosure of any discoveries or inventions. Most frequently, this is accomplished by the completion and submission of a Final Invention Statement. For guidance on the appropriate form to complete, please contact your ORS Contract Administrator. This form should be completed by the PI and forwarded to ORS for approval. PLEASE DO NOT SUBMIT this form to CTT. On your final invention statement list any invention for your particular grant number that was reported and filed through CTT. All information is confirmed with CTT. If the information on the form does not match the information on file with CTT, processing of your documentation will be delayed. To avoid delays please be sure to list all inventions under the relevant grant number.

2. **Relinquishing Statement:**
   This form is often required when transferring an award from one institution to another. For guidance on the appropriate form and process required by the specific sponsor, please contact your ORS Contract Administrator or Accountant.

   Estimate the balance left on the grant. All financial information provided on the forms will then need to be confirmed with your ORS Accountant. Also, all federal contracts and some grants require a final inventory of equipment (exceeding $5000 in initial cost) purchased under the grant. Forms may be delayed if there is incomplete or inaccurate information on whether equipment was bought under the grant.

   Please do not sign this document. This document must be signed by an ORS Post Award Accounting Manager and a Pre Award Official.

   Any PI with active awards who is planning to leave the University should contact ORS immediately to ensure a timely transfer of all awards. For further information please see the Research Services website, look for the Project Closeout Procedures bullet.

Upcoming Training Opportunities for Research Administrators

http://www.srainternational.org/newweb/meetings/annualmeeting/index.cfm

National Council for University Research Administrators (NCURA) Annual Meeting, November 3-6, 2002  http://www.ncura.edu/meetings/44/
A FEW QUICK REMINDERS
WHEN PREPARING BUDGETS FOR A CLINICAL TRIAL

Study budgets and payment schedules for clinical trials are generally negotiated between the Principal Investigator (or designated staff member) and the Sponsor. The budget is then approved by the Department Chair and Dean. Usually Sponsors provide a certain payment or reimbursement per patient which the PI converts into a budget with direct costs broken down into personnel, expendables, and the like. Before “backing into” the Sponsor’s proposed budget, PI’s should prepare an actual cost budget based on protocol requirements, time necessary to perform the activities, etc.

Recruitment of the maximum number of patients is not guaranteed and the actual payment received from a Sponsor may be less than projected. When calculating budgets for clinical trials, the individual negotiating the budget must ensure that indirect costs are included in the final numbers and that they are calculated according to the University F&A rate for clinical trials (currently 23.6%).

When reviewing the proposed payment schedule, an upfront payment (e.g. 25% of proposed budget) should be incorporated into the payment schedule to cover startup costs associated with the study, since significant expenditures are made prior to actual study initiation. In some cases, it is appropriate for startup costs to be nonrefundable. Note that Sponsors are not always willing to agree to upfront payments clauses because they see payment schedules as a method of enforcing their enrollment goals. For example, Sponsors may seek to ensure enrollment and data delivery by tying payments to certain milestones, such as patient enrollment. This is acceptable if the terms are reasonable, and include some upfront payment.

The Final payment from a Sponsor can be a potential issue in negotiations. Although it is reasonable to include some performance criteria for final payment, it is important to avoid terms that permit the Sponsor to disallow some of the patient reports or other deliverables, if the investigator has met a “best efforts” standard. It is preferable to avoid terms that preclude payment for patients not completing the study or not meeting enrollment criteria, or reports that are unilaterally not deemed satisfactory by the Sponsor.

In this time of thorough oversight in all aspects of clinical trials, it is very important to carefully distinguish between “standard of care” costs and research-related costs. “Standard of care” costs are generally associated with the treatment of a patient as part of their standard medical care that would have been conducted in the absence of a clinical trial. Such costs are normally charged to a third party payer, such as the government or a patient’s private insurance. Research-related costs are those charged to the Sponsor of the clinical trial which have previously been approved by the Sponsor. Payments from a Sponsor for the treatment of adverse events due to a patient’s participation in a clinical trial are also considered research-related costs. When ordering clinical or laboratory procedures, patient care costs must be billed to the appropriate account. Errors in such matters may create a substantial liability for the University of Pennsylvania and the Department.

If you have any questions, please contact Donald Deyo, Esq., Senior Associate Director, ORS, or Marcia Markowitz, Director, Clinical Research Development, OHR. Don can be reached by phone at (215) 573-9970 or by email at deyo@pobox.upenn.edu. Marcia can be reached by phone at (215) 746-7406 or by email at mmarkowi@mail.med.upenn.edu.

Attention to All Business Administrators Responsible for Service Centers:

All service center budgets (copy of BEN 100 Report) and fees for services are required to be submitted to Research Services each year according to the University Sponsored Projects Policy 2115. Business Administrators responsible for a service center should submit the budget and rate schedule to Bob McCann as soon as possible.
Office of Research Services

Contracts: Where Does a PI Go?

To ensure that funds provided from external sources to support research and other projects are administered in accordance with University policies as well as those of the sponsor, all externally sponsored projects for research or other related purposes are administered through the Office of Research Services (ORS). External sources include both governmental and private organizations. Accordingly, research contracts and grants are reviewed and approved through ORS.

In some cases, review and approval of corporate contracts are administered through other offices. A summary is given here:

**Clinical Trial Agreements:** All Clinical Trial Agreements are reviewed, negotiated and approved by ORS. [http://www.upenn.edu/researchservices/](http://www.upenn.edu/researchservices/)

**Sponsored Research Agreements:** Sponsored Research Agreements are reviewed, negotiated and approved by ORS. [http://www.upenn.edu/researchservices/](http://www.upenn.edu/researchservices/)

In cases where a Sponsored Research Agreement is being negotiated in conjunction with a licensing agreement, the Center for Technology Transfer (CTT) shall be responsible for conducting the negotiations, in consultation with ORS. [http://www.finance.upenn.edu/ctt/](http://www.finance.upenn.edu/ctt/)

**Confidentiality Agreements (except for those involving preliminary discussions with corporate sponsors of clinical trials):** Confidentiality Agreements are reviewed by CTT. [http://www.finance.upenn.edu/ctt/](http://www.finance.upenn.edu/ctt/)

**Confidentiality Agreements for Clinical Trials:** The review of Confidentiality Agreements from corporate sponsors which are used to cover a PI’s initial review of materials from a sponsor (such as the investigator’s brochure), prior to the actual decision to participate in a corporate sponsored clinical trial, is conducted by the Office of Human Research (OHR). These agreements are signed only by the PI. [http://www.med.upenn.edu/ohr/](http://www.med.upenn.edu/ohr/)

**Material Transfer Agreements:** CTT reviews, negotiates and approves all Materials Transfer Agreements, except those involving human tissue transfer. [http://www.finance.upenn.edu/ctt/](http://www.finance.upenn.edu/ctt/)

**Human Tissue Transfer Agreements:** These agreements are reviewed and approved by the Office of General Counsel (OGC). [http://www.upenn.edu/ogc](http://www.upenn.edu/ogc). Transfers of human tissues require approval from the Office of Regulatory Affairs (ORA). [http://www.upenn.edu/regulatoryaffairs/](http://www.upenn.edu/regulatoryaffairs/)

**Patent, Trademark and Software Licenses:** All such agreements are reviewed, negotiated and approved by CTT. [http://www.finance.upenn.edu/ctt/](http://www.finance.upenn.edu/ctt/)

For further information, please contact Donald Deyo, Esq., Senior Associate Director, Corporate Contracts at deyo@pobox.upenn.edu.

NIH Institutes 6 Digit Grant Numbers

The growth of NIH funding has resulted in record numbers of grant applications and awards. The National Cancer Institute (NCI) reached a milestone in June with the assignment of application number CA99999. The next number assigned to NCI was the first at NIH to use 6 digits in its serial number. Application numbers are assigned sequentially within NIH Institutes and Centers. NIH does not anticipate other Institutes or Centers will reach six digits before FY2003.

Please note that in order to accommodate this change, a leading zero was added to all NIH grant numbers in the Research Services database and Ben Financials.
What is Cost Sharing?

Cost Sharing or matching refers to that specific portion of project or program costs that is not funded by the sponsor.

Types of Cost Sharing:

**Mandatory:** Mandatory cost sharing refers to those costs which are either required by the terms of the award, or by federal statute, that the University must contribute toward the project in order for an award to be made.

**Voluntary Committed:** Any cost associated with a project, which has been identified in the proposal, but for which funding has not been requested from the sponsor. Some common examples include a percentage of effort for faculty or senior researchers included in a proposal budget or stated in the text of the proposal for which compensation is not requested or the purchase of equipment for the project, identified in the proposal, for which funds have not been requested.

**Voluntary Uncommitted:** Any cost associated with a project and not funded by the sponsor, which has not been identified in the proposal, or in any other communication to the sponsor as a commitment of the University. Effort of faculty or senior researchers that is over and above that which is committed and budgeted for in a sponsored agreement, e.g., donated faculty effort on a project over and above that which was proposed for the project. Academic year effort on a project for which only summer salary was proposed also would be considered uncommitted cost sharing. If such effort was not listed either on the budget page, or in the body of the proposal.

**Matching:** Refers to the requirement of some sponsored projects that grant funds be matched in some proportion with non-sponsored project funds, or that the grantee participate to some extent in the cost of the project. Matching requirements may be in the form of an actual cash expenditure of funds, or may be an “in-kind” match, which is the value of non-cash contributions to the project.

For further information on cost sharing, including the appropriate identification, accounting, and reporting of it, please refer to Sponsored Projects Policy #2119 which can be found at [www.finance.upenn.edu/vpfinance/fpm/2100/2100_pdf/2119.pdf](http://www.finance.upenn.edu/vpfinance/fpm/2100/2100_pdf/2119.pdf) or contact your ORS Accountant.

Where can I get more information about administering my grants?

Office of Research Services Web Site: [http://www.upenn.edu/researchservices/](http://www.upenn.edu/researchservices/)

Research Investigator’s Handbook: [http://www.upenn.edu/researchservices/rih/intro.html](http://www.upenn.edu/researchservices/rih/intro.html)

A Quick Guide for Faculty: [http://www.upenn.edu/researchservices/pdfs/newfacbk.pdf](http://www.upenn.edu/researchservices/pdfs/newfacbk.pdf)

University of Pennsylvania Cost Sharing Policy: [http://www.upenn.edu/researchservices/rs/costshare.html](http://www.upenn.edu/researchservices/rs/costshare.html)

Contact an Office of Research Services Staff Member: [http://www.upenn.edu/researchservices/rs/contact.html](http://www.upenn.edu/researchservices/rs/contact.html)
Revised Assignments for Pre-Award Staff

Due to staff changes, there has been a reassignment of responsibilities for some departments/schools. The revised department assignments are detailed in the following listing. The Pre-award staff is responsible for processing proposals, reviewing, negotiating, and accepting awards (except for corporate contracts), as well as, providing post-award non-financial administration for these accounts. Questions concerning issues such as no-cost extensions, carryover requests and other administrative matters should be directed to the appropriate pre-award contact.

Please note that all questions concerning industrial clinical trial agreements and sponsored research agreements should be addressed to the Corporate Contracts Group. Greg Curley is now responsible for Account Information Sheets (AIS’s) for all industrial clinical trials and sponsored research agreements.

PAMELA S. CAUDILL - DIRECTOR  
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• Biomedical Graduate Studies – SOM  
• Biostatistics – SOM  
• Cancer Center – SOM  
• Center for Experimental Therapeutics – SOM  
• Institute for Environmental Medicine – SOM  
• Institute for Human Gene Therapy – SOM  
• Institute for Neurological Sciences – SOM  
• Medical Genetics – SOM  
• Neurology – SOM  
• Pathology & Laboratory Medicine  
• Rehabilitative Medicine – SOM

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• Center for Sleep and Respiratory Neurobiology – SOM  
• Institute on Age – SOM  
• Pennsylvania Muscle Institute – SOM  
• Pharmacology – SOM

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• School of Engineering and Applied Science  
• Wharton School  
• Graduate School of Education  
• University Museum  
• Emergency Medicine – SOM

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• Cardiology  
• Clinical Research Center – SOM  
• Diabetes – SOM  
• Endocrinology –SOM  
• Gastrointestinal – SOM  
• General Intestinal Medicine – SOM  
• Infectious Disease – SOM  
• Pulmonary, Allergy & Critical Care – SOM  
• Renal – SOM  
• Rheumatology – SOM

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• Cerebrovascular Research Center – SOM  
• Family Practice – SOM  
• Graduate School of Fine Arts  
• Obstetrics & Gynecology – SOM  
• Surgery – SOM  
• Psychiatry – SOM

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• Law School  
• Morris Arboretum  
• Provost Interdisciplinary Program  
• School of Art and Sciences  
• School of Social Work  
• Student Services  
• Van Pelt Library

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• Center for Aids Research – SOM  
• Genetics – SOM  
• Hematology/Oncology  
• Neurosurgery - SOM  
• Orthopedic Surgery – SOM  
• Pediatrics – SOM  
• Physiology – SOM  
• School of Medicine, Institute for Medicine & Engineering – SOM  
• Radiation Oncology  
• Radiology

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• Annenberg Center for Performing Arts  
• Annenberg School for Communication  
• Cell & Developmental Biology – SOM  
• Center for Bioethics – SOM  
• Dermatology  
• Geriatrics – SOM  
• Microbiology  – SOM  
• Ophthalmology – SOM  
• Otorhinolaryngology – SOM  
• School of Nursing  
• School of Veterinary Medicine

CORPORATE CONTRACTS GROUP:

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• Corporate Clinical Trial Agreements  
• Account Information Sheets for Corporate Contracts

GREGORY CURLEY – CONTRACT ADMINISTRATOR  
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• Account Information Sheets for Corporate Contracts
The main functions handled by these ORS staff members are the preparation of financial invoices and reports, coordination of audits, collection of receivables, cash management functions, and close outs of funds. The Federal Compliance Group handles facilities and administrative costs, employee benefit rates, effort reporting, and compliance issues. Contact Information for all areas is provided below.

FEDERAL COMPLIANCE GROUP:
ROBERT McCANN – DIRECTOR
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  • Center for Sleep
  • Muscle Institute
  • Physiology
  • Psychiatry
  • Radiation Oncology
  • Surgery
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  • Pathology
  • Pediatrics – Neonatology
  • Radiology
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  • Biomedical Graduate Studies
  • Dermatology
  • Institute for Environmental Medicine
  • Genetics
  • Institute of Neurological Sciences
  • Neurology
  • Neuroscience
  • Medical School
  • Ophthalmology
  • Orthopaedic Surgery
  • Otorhinolaryngology: Head and Neck Surgery
  • Pediatrics Admin
  • Pharmacology

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  • Center for Experimental Therapeutics
  • Institute for Human Gene Therapy
  • Institute for Aging
  • Molecular & Cellular Engineering
  • Center for Clinical Epidemiology and Biostatistics
  • Emergency Medicine
  • Family Practice
  • Anesthesia
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  • Linguistics
  • Physics
  • Fine Arts
  • Graduate School of Education
  • Law School
  • Morris Arboretum
  • University Museum
• School of Medicine Departments:
  • Center for Bioinformatics
  • Institute for Medicine & Engineering
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• School of Arts & Sciences:
  • All except Chemistry, Linguistics, and Physics
• The College
• General University
• School of Social Work
• Van Pelt Library
• Wharton School
• School of Medicine Departments:
  • Diabetes
  • Rehabilitation Medicine

RECEIVABLES:
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About Our Organization...

Our Mission

The Office of Research Services (ORS) was established in April 1998, through merger of the Office of Research Administration with the Research Accounting and Federal Compliance sections of the Office of the Comptroller. The Office of Research Services oversees the administrative support of the University’s externally funded research and is responsible for implementation of University policies established for this purpose. An important part of the ORS mission is service to the research faculty, through the provision of information and advice for the development of applications, and assistance in the administration of awarded grants and contracts.

In this role, Research Services

- Supports the schools and centers in the development of proposals for grants and contracts
- Reviews and approves all proposals before submission to the potential sponsor
- Coordinates negotiations of awards
- Accepts awards for the University, including the signing of contracts
- Provides oversight and guidance to faculty and staff concerning the proper management of sponsored projects
- Prepares all financial reports to sponsors

In addition to these functions, Research Services is responsible for billing of contracts management of letters of credit for payment of grants, preparation of indirect cost and employee benefit rate proposals and rate negotiations, management of the effort reporting system, and oversight of service center rate development.

The office reports jointly to the Vice President for Finance and Vice Provost for Research.

Treasury Offset Program Notices

Please be aware that the Department of the Treasury has been offsetting funds due to the University and forwarding them to the Philadelphia VAMC. If you receive a notification that any funds which were due to the University have been offset, please fax a copy of the notice to the attention of Kerry Peluso at 215-898-0403.

Office of Research Services Quick Contact List:


Andrew B. Rudczynski, Ph.D., Associate Vice President for Finance And Executive Director, Research Services: 215-573-9249, abrud@pobox.upenn.edu

Pamela Caudill, Director of Pre Award Non-Financial Administration: 215-573-6706, caudill@pobox.upenn.edu

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Robert McCann, Director of Cost Studies: 215-898-1469, mccannr@pobox.upenn.edu

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