

Partners HealthCare System (PHS) Contracting Guidelines
Research Ventures & Licensing (RVL), Partners Clinical Research Office (PCRO),
Research Management Grants and Contracts (G&C) and Materials Management

GENERAL OVERVIEW

PHS Research Ventures & Licensing (RVL)

<http://rvl.partners.org/>

RVL enables the commercialization of new technologies from Partners' academic medical centers by bringing together specialists in technology licensing, research contracts, ventures and business development, and partnering with investigators, scientists and clinicians. RVL coordinates all commercialization services across Partners.

Primary Functions:

- Manages inventions arising from research
- Protects intellectual property (IP)
- Determines commercialization pathway
- Finds industry partners and licensees
- Identifies technology funding options
- Creates marketing plans
- Supports PHS academic-industry alliances
- Develops and negotiates industry-sponsored research agreements for basic research
- Negotiates agreements for proprietary materials
- Oversees personal consulting policy compliance

Partners Clinical Research Office (PCRO)

www.partners.org/pcro/

PCRO is responsible for developing, negotiating and executing agreements and budgets for industry-sponsored clinical research for Partners.

Primary Functions:

- Develops, negotiates and executes agreements and budgets for industry-sponsored clinical research
- Prepares Medicare coverage analyses (MCA) for all clinical trials
- Prepares and submits Category B Investigational Device Exemption (IDE) petitions to Medicare

PHS Research Management Grants & Contracts

<http://resadmin.partners.org/>

Research Management Grants and Contracts is responsible for developing, negotiating and executing agreements for all awards funded by federal and state agencies, foundations and not-for-profit entities (NPE).

Primary Functions:

- Conducts proposal review and submission including budget review and development, cost share approval and coordination of potential Conflicts of Interest
- Negotiates, manages and executes agreements for sponsored research funded through federal and state agencies, foundations and not-for-profit entities (NPE)
- Develops, negotiates and executes outgoing sub-contracts for sponsored research awards
- Ensures compliance with federal, state and sponsor-specific requirements
- Ensures compliance with PHS and hospital specific policies
- Participates in budgeting process for industry awards by reviewing and approving overhead calculation
- Account set-up, financial oversight and reporting and invoicing

PHS Materials Management

<http://pulse.partners.org/mm/index.htm>

Partners Materials Management serves the research and clinical community by locating and procuring cost-effective products and services. The Materials Management Department contracts with vendors and suppliers to procure items and/or services for sponsored projects including consultants, data management, lab tests or eye exams. Purchasing is subdivided into the following five teams:

1. **Capital:** This team handles all capital purchases that are stand-alone items valued at \$5,000 or more, with a life expectancy of at least two years, and all computer equipment, software and furniture requests.

2. Commodities: This team procures most of the day-to-day operational products and services, including ordering linens, books, and film, as well as non-capital equipment. They also contract for repairs and services.
3. Customer Service: This team is committed to delivering exceptional services to the research community. They anticipate customer needs in the delivery of timely, accurate and cost-effective services.
4. Medical/Surgical: This team orders all patient-care supplies and procures all medical and surgical products, implants and surgical instruments. They primarily serve the Partners clinical community.
5. Research: This team orders all supplies used in laboratory environments (e.g., test tubes and media, chemicals, reagents, radioisotopes, etc.).

Primary Functions:

- Procures materials, supplies and services paid from institutional funds, sundry funds and/or research sundry funds
- Negotiates consulting agreements, including requests for quotations
- Executes contractual agreements

PRIMARY EXPERTISE

RVL

- Scientific expertise regarding IP
- Licenses to patents and know-how (research information)
- Product liability indemnification

PCRO

- Human subject protection and Institutional Review Board (IRB)
- Patient confidentiality, data privacy, HIPAA (Health Insurance Portability and Accountability Act)
- Subject injury and indemnification

Grants & Contracts

- Federal/State terms and conditions
- Payment terms and invoicing

Materials Management

- Negotiating, managing and executing consulting and contractor agreements
- Procuring research supplies and services

Shared

- Conflicts of Interest
- Access to data/publications
- Confidentiality of data

CROSSOVER PROJECTS

On occasion, some agreements contain terms that require the input and collaboration of RVL, PCRO, Grants and Contracts and/or Materials Management. In the majority of these cases, the “lead” group is responsible for structuring and coordinating the negotiations and the “support” group is responsible for providing guidance and agreement language relevant to a particular area of expertise. The examples below outline “gray area” scenarios where the involvement of more than one office is required to execute and manage an award.

I. Foundation award

Lead: Grants and Contracts

Support: RVL provides support for terms such as IP, sharing of results, confidentiality and publication provisions and provides IP clarification letters to Grants and Contracts, if necessary; PCRO provides support for human subject/clinical research-related terms

II. Incoming sub-contract

A. *Federal award to industry with sub-contract to Partners entity (e.g., Small Business Innovation Research, SBIR; Small Business Technology Transfer, STTR)*

Lead: RVL for basic research; PCRO for clinical research

Support: Grants and Contracts provides support for federal language

B. Industry award to an NPE with sub-contract to Partners entity

Lead: Grants and Contracts

Support: RVL for basic research agreement with respect to IP provisions; PCRO for human subject/clinical research-related terms

Notes: May not be negotiable once NPE agrees to industry terms
Unacceptable language must be escalated to VP for exception decisions

C. Foundation award to an NPE with sub-contract to Partners

Lead: Grants and Contracts

Support: RVL for basic research agreement with respect to IP provisions; PCRO for human subject/clinical research-related terms

Notes: May not be negotiable once NPE agrees to foundation terms
Unacceptable language must be escalated to VP for exception decisions

D. NPE/federal/state award to an NPE with sub-contract to Partners entity

Lead: Grants and Contracts

Support: RVL for basic research agreement with respect to IP provisions; PCRO for human subject/clinical research-related terms

Notes: May not be negotiable once the immediate NPE agrees to original NPE/federal/state terms
Unacceptable language must be escalated to VP for exception decisions

III. Outgoing sub-contract

A. Industry award for basic research to Partners entity with sub-contract out to any type of entity

Lead: RVL for basic research; PCRO for clinical research

B. Industry award for clinical research to Partners entity with sub-contract out to any type of entity

Lead: PCRO

C. Foundation award to Partners entity then sub-contract out to any type of entity

Lead: Grants and Contracts

D. NPE/federal/state award to Partners entity then sub-contract out to any type of entity

Lead: Grants and Contracts

IV. Service agreements, consulting agreements and sub-contracts out paid from institutional funds

Lead: Materials Management

Support: Grants and Contracts; RVL with respect to IP provisions; PCRO for human subjects/clinical research-related terms

Note: If the service is deemed to be a research collaboration that requires a sub-contract from Grants and Contracts, the VPs of Research and Development and hospital CFOs must approve

V. Personal Consulting Policy Review

Lead: RVL

CONTACTS

Contact your RVL Case Manager, PCRO Agreement Associate or Contracts Manager with any questions. These individuals and teams will work together to determine the appropriate steps to take for complex agreements.

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