



Request for Proposal (RFP)

PCORI

Survey Research Services

**PCORI**

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**SECTION 1 THE SCHEDULE**

**Survey Research Services  
RFP #PCO-SRVRSH2012  
Request for Proposal (RFP)**

**1.0 Background**

The Patient-Centered Outcomes Research Institute (PCORI) was created to conduct research to provide information about the best available evidence to help patients and their healthcare providers make more informed decisions. PCORI's research is intended to give patients a better understanding of the prevention, treatment, and care options available, along with the science that supports those options.

PCORI works to ensure partnerships between patients and other stakeholders with researchers in all aspects of patient-centered outcomes research (PCOR), including topic generation, research prioritization, study design, sample recruitment and project implementation, analysis, and dissemination of results. PCORI supports research on methods to understand optimal approaches for identifying and addressing PCOR questions and optimal approaches to patient and other stakeholder engagement in research. PCORI is committed to collaborating with patients, other stakeholders, and subject matter experts in patient-centered outcomes research to advance the PCORI research agenda and overall mission.

**2.0 Description**

PCORI is soliciting proposals from Contractors who can provide survey research services.

**3.0 Pricing Requirements**

The Contractor shall provide a pricing proposal that supports the following estimated requirements:

Line Item	Survey Research Services	Type	Quantity	Hours	Unit Price	Pricing
0001	Survey & Research	FFP	1			

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**SECTION 2 PERFORMANCE WORK STATEMENT (PWS)**

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**RFP #PCO-SRVRSH2012  
SCHEDULE OF SUPPLIES/SERVICES****1.0 Scope of Work**

1.1 The Contractor shall provide survey research services for PCORI's Scientific Team. The Contractor shall produce two distinct surveys and analyze and report the results of the surveys as outlined in the following paragraphs. These surveys will serve to support PCORI's ongoing efforts in evaluating engagement of patients and clinicians in patient-centered outcome research (PCOR) and in evaluating the impact of comparative effective research on healthcare decisions.

**2.0 Contractor Requirements for Providing Survey Research Services****2.1 Task 1**

2.1.1 The Contractor will develop a plan that includes an approach to the efficient recruitment of patients and caregivers utilizing the available networks of patient/caregiver organizations, online communities, bloggers and list serves, and community-based clinicians. The Contractor should provide evidence of optimal response rates for healthcare sector surveys.

**2.2 Task 2**

2.2.1 The Contractor will work closely with the PCORI staff to develop and design two survey instruments, one for clinicians, targeting those in community-based practice, and one for patients/caregivers, including past and potential future users of health care. For each target population, Contractor will develop a plan, in plain language, for survey design, implementation, data collection, and response rate monitoring. The Contractor should recommend a process for optimizing response rate. Human subjects approval should be included.

**2.3 Task 3**

2.3.1 The Contractor will create an analysis plan to include comparison of respondents and nonrespondents on key variables, recommended subset analyses, and recommended format for presentation of results to research audiences and to general audiences. The Contractor will provide a plan for real-time analysis of results and include recommended tables and figures for presentation of results to research (technical) and non-technical audiences.

**2.4 Key Objectives of Survey Research Services****2.4.1 Key objectives of patient surveys are to:**

- Obtain opinions on the feasibility and desirability of patient-centered outcomes in scientific research
- Assess respondents' prior experience with patient-centered outcomes
- Obtain suggestions for optimizing effective interactions between patients and researchers
- Identify and rank order barriers and facilitators of patient engagement in research

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- Assess general interest in becoming a patient member of a research team that could result in better patient outcomes for themselves and others
  - Evaluate patient ratings of the potential impact of patient-centered outcomes on interactions with clinicians and on healthcare decision-making
  - Evaluate use of comparative clinical information in patient interactions with clinicians
  - Identify information sources used by respondents in healthcare decision-making

#### 2.4.2 Key objectives of clinician surveys are to:

- Obtain opinions on the feasibility of patient engagement in research
- Assess respondents' prior experience with conducting comparative effectiveness research (CER)
- Assess respondents' prior experience with using CER to guide clinical decisions
- Assess respondents' familiarity with and prior experience with PCOR
- Obtain suggestions for optimizing effective interactions between patients and researchers
- Rank order barriers and facilitators of patient engagement in research
- Evaluate potential impact of PCOR to respondents' clinical decision-making
- Evaluate the potential impact of CER on respondents' clinical decision-making

## 2.5 Project Management

The Contractor shall provide personnel and any technology or equipment necessary to assure that the highest quality of service is provided. The Contractor shall have the capability to provide the services required, meet all deadlines, and submit reports in order for PCORI to utilize this information in further development of its programs. All Contractor personnel providing services under this contract shall be fluent in English and meet the following requirements. All key personnel shall be available to start on the contract start date.

### 2.5.1 Key Personnel

#### 2.5.1.1 Project Manager

The Contractor shall provide a Project Manager who shall be responsible as the Point of Contact (POC) for PCORI. The Project Manager shall have experience in the management of survey research services and shall have adequate authority to make decisions for the timely resolution of problems. The Project Manager shall coordinate closely with the PCORI Engagement Research Team.

### 2.5.2 Other Staff/Subcontractors

The Contractor shall propose how it will staff the Survey Research Services to support PCORI's needs to include all services described in this scope of work. The Contractor shall demonstrate its ability to support the variety of requests from PCORI and present its problem resolution method. The Contractor shall flow down all terms and conditions of the contract to any and all subcontractors.

**3.0 Onsite Support**

No onsite support is required.

**4.0 Furnishing of Equipment/Property**

PCORI will not be furnishing any equipment or property for this contract.

**5.0 Period of Performance**

The period of performance is a one-time effort. Anticipated contract award date is approximately 21 days from due date of RFP.

Project-Based

23 July 2012 – 15 September 2012

**6.0 Contractor’s Quality Control and Quality Assurance Surveillance Plan**

6.1 The Contractor shall describe the procedures to continually monitor the quality of services with the goal of providing and maintaining the highest level of customer service and satisfaction. These procedures should include:

- An internal method for monitoring, identifying, and correcting deficiencies in the quality of service furnished to PCORI
- A Quality Service survey form that addresses the services to be furnished under this contract

6.2 The Contractor should describe and outline its procedures to ensure that the integrity of the information surveyed, researched, and collected remains contained.

6.3 It is PCORI’s intent to develop Service Level Agreements (SLAs) for this effort. The SLAs will be developed post award and as mutually agreed between the Contractor and PCORI. The SLAs, once established, may be subject to change as the program progresses and matures.

6.4 Quality Assurance Surveillance Plan (QASP)

As a performance-based contract, the Contractor will be required to perform at an acceptable level of quality, at the minimum, to continue supporting the contract. Should the Contractor be unable to meet the requirements, the contract may be canceled due to unsatisfactory performance. The following quality guidelines will be used to measure Contractor performance. These guidelines are subject to change, if it is in the best interest of PCORI.

Quality Measurement	Quality Level		
	Exceeds	Acceptable	Unacceptable
Responding to PCORI Inquiries	Answers within 12 hours	Answers within 48 hours	Answers in more than 48 hours
Surveys	Plain language, readable, excellent flow, logical, informational, well-stated and crafted—96% accuracy	Plain language, good flow, logical, informational, crafted well, but with 90% – 95% accuracy	Fragmented, illogical, poorly crafted and with less than 89% accuracy

<b>Reports and Recommendations</b>	Plain language, readable, excellent flow, logical, informational, well-stated and crafted—96% accuracy	Plain language, good flow, logical, informational, crafted well, but with 90% – 95% accuracy	Very technical, fragmented, illogical, poorly crafted and with less than 89% accuracy
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## 7.0 Deliverables

The Contractor shall provide the following deliverables/submittals within the time frames identified below:

<b>Deliverable</b>	<b>Due Date</b>	<b>Method</b>
<b>Recruitment Plan Patients and Clinicians</b>	July 26, 2012	Send electronically to Director of Engagement Research
<b>Draft Survey Items and Draft Analysis Plan</b>	August 1, 2012	Send electronically to Director of Engagement Research
<b>Patient Survey (Implementation, Data Collection, and Response Monitoring)</b>	August 3–14, 2012	Send electronically to Director of Engagement Research
<b>Clinician Survey (Implementation, Data Collection, and Response Monitoring)</b>	August 3–14, 2012	Send electronically to Director of Engagement Research
<b>Final Analysis Plan and Recommendations</b>	September 15, 2012	Send electronically to Director of Engagement Research
<b>Ad-hoc</b>	PCORI may request special reports to be developed over the course of the contract with the data collected through the various channels (online, messaging, or phone)	Send electronically to Director of Engagement Research and/or PCORI Staff member

### 7.1.1 Management Reports and Deliverables

The Contractor shall provide PCORI with management information reports. At a minimum, the Contractor shall develop the following reports at the conclusion of the contract.

- **Problem and Resolutions Report:** A concise quarterly narrative (no more than one page) of the Contractor's activities. This report shall identify problems and recommend solutions. The report shall include suggestions to enhance service,

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where appropriate. PCORI encourages interim reports, as deemed necessary by the Contractor.

- Patient Survey: A survey (15 to 30 items) for patients living with chronic conditions that reflects the key objectives described above.
- Clinician Survey: A survey (15 to 30 items) of community-based health services providers that reflects the key objectives described above.
- An analysis plan comparing respondents and non-respondents on key variables, recommendations for specific subset analyses, and recommendations for format for presentation to various audiences.

The Contractor must consider electronic methods of communication of report information in order to minimize or eliminate unnecessary paperwork.

## **8.0 Place of Performance**

The Contractor is required to provide its own offices to be used to provide the services required hereunder.

## **9.0 Hours of Service**

The Contractor shall maintain normal hours of operation Monday through Friday between 9:00 a.m. and 5:30 p.m. Eastern Time. PCORI has regular observance of federal holidays:

New Year's Day
Birthday of Martin Luther King, Jr.
Washington's Birthday
Memorial Day
Independence Day
Labor Day
Columbus Day
Veterans Day
Thanksgiving Day
Christmas Day

## **10.0 Type of Contract**

Firm Fixed Price (FFP): This will be offered on a firm, fixed price basis. The Contractor shall recommend the labor mix and hours to complete the project by the due date.

## **11.0 Insurance**

The Contractor, at its own expense, shall provide and maintain insurance during the entire period of performance of this contract. See [Section 5, paragraph 2](#).

## **12.0 Compliance**

### **12.1 Forms, Rules, Regulations, and Procedures**

Contractor is to comply with PCORI's Rules and Regulations, all required forms, and any changes in procedures. Contractor will remain informed of any such changes and updates, as necessary, by the PCORI Finance Department (FD).

### **12.2 Section 508 Compliance**



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Upon the request of employees or other persons with disabilities participating in various capacities with PCORI, the Contractor must arrange necessary and reasonable accommodations, and ensure that the impaired individuals have the necessary information to make their participation and time without incident.

12.3 Use of Proprietary Data/Technology/Information

[See Attachment 1.](#)

12.4 Use of Contracted Work

The services and information generated under this contract become the property of PCORI. PCORI retains the rights to use these materials in whole or in part. The Contractor and its staff and/or subcontractors are not permitted to use information created during the course of this contract without authorized permission by PCORI. For more information, see [Attachment 1.](#)

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**SECTION 3 SOLICITATION PROVISIONS**

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**Instructions to Offerors****1.0 Summary of Instructions**

Each proposal must consist of the following:

- 1.1 **Format.** Arial or Times New Roman Font no less than 11 points with 1-inch margins, single spaced, graphics and tables are acceptable; MS Office or Adobe PDF formats.
- 1.2 **Cover Letter.** The Offeror shall include a cover letter that contains the following information:
  - Offeror's name and mailing address
  - Reference to the solicitation number
  - Technical and contract points of contact—name, phone number, and e-mail address
  - Business size (large, small, state/federal certifications—MBE, 8(a), HUBZone, etc)
  - Dunn & Bradstreet Number (DUNS)
  - Federal Tax ID (EIN, TIN, SS)
  - Validity of quote for 60 days
  - A statement specifying the extent of agreement with all terms, conditions, and provisions included in the solicitation and agreement to furnish any or all items upon which prices are offered at the price set opposite each item
  - Acknowledgement of any amendments by reference number
- 1.3 **Technical Solution.** The Offeror shall demonstrate and describe the proposed solution based on the requirements in the PWS. The submission shall be no longer than 10 pages.
  - 1.3.1 **Sample Task Order (TO).** In addition to the response required relative to the PWS, the Offeror shall provide a Sample TO of previous work to demonstrate capabilities and approach to providing survey support services, including survey development, implementing, data collection, analysis, and reporting for patient and clinician groups.
- 1.4 **Management Approach.** The Offeror shall demonstrate that it has the ability to manage and control the operation to ensure successful program support, including subjects such as the program management, financial resources or ability to obtain them, equipment and facilities, quality approach, internal controls, and staffing. This section should be no more than five pages.
  - 1.4.1 Key personnel resumes should be no longer than two pages and are not included in the page count.
- 1.5 **Past Performance.** The Offeror shall identify up to three previous or existing clients within the last five years with a similar effort in the non-profit, commercial, or federal market. Include client name, period (dates) of performance, point of contact (POC), POC name/e-mail/phone number, and summary of work performed.
- 1.6 **Cost Proposal.** Survey Research Services for the events described in Section 1.0, paragraph 3.0. The Offeror should describe one set of cost line item numbers:
  - 1.6.1 Item 0001: Firm Fixed Price basis; labor mix and hours prepared by Contractor

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- 1.7 Questions to be addressed and submitted to [rfp@pcori.org](mailto:rfp@pcori.org) with reference to the solicitation number in the subject line due by July 2, 2012, 2:00 pm Eastern Time.
  - 1.8 E-mail responses to [rfp@pcori.org](mailto:rfp@pcori.org) with reference to the solicitation number in the subject line.
  - 1.9 Due date for proposal: 2:00 pm Eastern Time, July 10, 2012.
  - 1.10 Anticipated award date for quote: July 17, 2012.

## **2.0 Withdrawal or Modification of Proposals**

An Offeror may modify or withdraw its proposal upon written or electronic notice, or facsimile transmission, if received at the location designated in the solicitation for submission of proposals, but not later than the closing date and time for receipt of proposals.

## **3.0 Late Submissions**

A late proposal or late request for modification or late request for withdrawal shall not be considered, unless a late modification of a successful proposal makes its terms more favorable to PCORI.

## **4.0 Retention of Proposals**

All proposal documents shall be the property of PCORI and retained by PCORI, and therefore shall not be returned to the Offerors.

**SECTION 4 EVALUATION FACTORS**

- 1.0 Award will be made to the Offeror who proposes a best value proposal, as determined by the procedures outlined in the previous sections.
- 2.0 PCORI reserves the right to reject proposals that are unreasonably low or high in price. Price will be evaluated for cost realism.
- 3.0 The price will be determined with regard to the fulfillment of the requirements based on Section 1.
- 4.0 PCORI will determine Offeror’s acceptability by assessing the Offeror’s compliance with the terms of the RFP.
- 5.0 Competition is open to any size vendor, but points will be awarded for small business participation.

Matrix

Transaction Description	Weight of Rating Factor
Technical Proposal	40%
Management Approach	30%
Past Performance	20%
Cost Proposal	10%

Evaluation Categories

Outstanding—The Offeror has demonstrated that there is a high probability of success in a combination of past results, low risk, and professional distribution of services.

Good—The Offeror has demonstrated that there is a good probability of success in a combination of past results, moderate risk, and professional distribution of services.

Fair—The Offeror has demonstrated that there is marginal probability of success in a combination of past results, marginal risk, and professional distribution of services.

Poor—The Offeror has not demonstrated that there is a probability of success in this services-based effort.

**6.0 Best and Final Offers (BAFO)**

Subsequent to receiving original proposals, PCORI reserves the right to notify all technically acceptable Offerors within the competitive range and to provide them an opportunity to submit written best and final offers at the designated date and time. BAFOs shall be subject to the Late Submissions, Late Modifications, and Late Withdrawals of Proposals provision of the solicitation. After receipt of BAFO, no discussions shall be reopened unless the FD determines that it is clearly in PCORI’s best interest to do so; for example, it is clear that information available at that time is inadequate to reasonably justify Contractor selection and award based on the BAFOs received. If discussions are reopened, the FD shall issue an additional request for BAFOs to all technically acceptable Offerors still within the competitive range.

**7.0 Oral Presentations**

At its discretion, PCORI reserves the right to also invite Offerors who are technically acceptable to conduct a presentation to PCORI on the proposed effort for technical and management approaches

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identified in the submission. PCORI will notify vendors who meet the qualifications and provide the date, time, and format for the presentation.

## **8.0 Protests**

Any actual or prospective Offeror, or contractor who is aggrieved in connection with the solicitation or award of a contract, must file a protest with PCORI's FD, no later than 10 business days after the basis of protest is known or should have been known, whichever is earlier. A protest based on alleged improprieties in a solicitation that are apparent prior to proposal opening or the time set for receipt of initial proposals shall be filed with the FD prior to proposal opening or the time set for receipt of initial proposals. In procurements in which proposals are requested, alleged improprieties that do not exist in the initial solicitation, but are subsequently incorporated into the solicitation, must be protested no later than the closing time for receipt of proposals following the incorporation. The protest shall be filed in writing, with the FD.

Protests should be submitted to [finance@pcori.org](mailto:finance@pcori.org) or mailed to:

PCORI  
Attn: Finance Department  
1828 L St., NW, Suite 900  
Washington, DC 20036

## **9.0 Non-disclosure Agreements (NDA)**

The Contractor shall not release any sensitive, confidential, or proprietary information, without prior written approval from PCORI. At the time of award, the Awardee will be required to sign an NDA, and at each subsequent option year, if exercised.

## **10.0 Organizational Conflict of Interest (OCOI)**

The Contractor, upon award, shall sign a statement confirming that it does not have and will prevent any organizational conflict of interest. If a conflict arises, the Contractor will immediately advise PCORI.

**SECTION 5 POST AWARD INFORMATION**

**1.0 Post Award Conference/Kickoff Meeting**

Upon notice of award, PCORI will coordinate an Award Kickoff Meeting within 10 days with the Awardee. Date, time, and location will be provided at the time of the award.

**2.0 Documentation Requirements**

2.1 Certifications, permits, licenses. The Awardee may be required to provide documentation to support its legal ability to operate facilities in the U.S.

2.2 Insurance. The Awardee hereby assumes absolute responsibility and liability for any and all personal injuries or death and/or property damage or losses suffered due to negligence of the Contractor's personnel in the performance of the services required under this contract.

The Awardee, at its own expense, agrees to provide and maintain the requisite insurance in support of this contract for the entire duration, including option years, with the following minimum coverage:

Type of Insurance	Limits of Liability
General Liability	\$1,000,000

**3.0 Notice to Proceed**

3.1 Immediately upon receipt of notice of award, the Contractor shall take all necessary steps to prepare for performance of the services required hereunder. The Contractor shall have a maximum of seven calendar days to complete these steps.

3.2 Following receipt from the Contractor of acceptable evidence that the Contractor has obtained all required licenses, permits, and insurance and is otherwise prepared to commence providing the services, PCORI shall issue a Notice to Proceed.

3.3 On the date established in the Notice to Proceed (this notice will allow a minimum of seven calendar days from the date of the Notice to Proceed, unless the Contractor agrees to an earlier date), the Contractor shall start work.

**4.0 Period of Performance and Option Years**

The performance period of this contract is from the start date established in the Notice to Proceed and continuing for a one-time effort project-based contract from 23 July 2012 – 15 September 2012. The initial period of performance includes any transition period authorized under the contract.

**5.0 Basis of Compensation to the Contractor**

This is a Firm Fixed Price contract. Any Contractor quality issues that result in the re-drafting of work or increased labor required to meet deliverables during the performance of the contract are the financial responsibility of the Contractor and re-work will be done at the Contractor's expense.

**6.0 Billing and Payment Procedures**



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PCORI prefers electronic means of invoicing. Invoices shall be provided to the Finance Department at:

- Project Payments Based on Milestone/Deliverable
- Every 30 days

Billing address:

PCORI

Attn: Finance Department  
1828 L St., NW, Suite 900  
Washington, DC 20036

E-mail: [finance@pcori.org](mailto:finance@pcori.org)

#### **7.0 Refund Procedures**

Not applicable.

**SECTION 6 DEFINITIONS AND ACRONYMS**

Term	Definition
<b>Business Day</b>	Monday through Friday, 9:00 am – 5:30 pm Eastern Time
<b>FD</b>	Finance Department
<b>PCORI</b>	Patient-Centered Outcomes Research Institute
<b>POC</b>	Point of Contact
<b>PWS</b>	Performance Work Statement
<b>QASP</b>	Quality Assurance Surveillance Plan; intended to ensure the qualitative success of the performance of the contract with measurements and monitoring by PCORI
<b>Section 508</b>	Section 508 requires that federal agencies' electronic and information technology is accessible to people with disabilities: <a href="http://www.section508.gov">www.section508.gov</a>
<b>SLA</b>	Service Level Agreement; a binding agreement for the level of service or quality of performance the Contractor commits to PCORI
<b>TO</b>	Task Order; an order requested by PCORI to the Contractor to obtain an estimate of work and hours to be conducted on a specific project or assignment



**SECTION 7 ATTACHMENTS**

**Attachment 1 (Optional where integrity of data, information, or technology needs to be protected)**

**Restrictive Markings for Proposals**

Offerors that include in their proposals data that they do not want disclosed to the public for any purpose, or used by PCORI except for evaluation purposes shall:

- a) Mark the title page with the following legend: “This proposal includes data that shall not be disclosed outside PCORI and shall not be duplicated, used, or disclosed—in whole or in part—for any purpose other than to evaluate this proposal. If, however, a contract is awarded to this Offeror as a result of—or in connection with—the submission of this data, PCORI shall have the right to duplicate, use, or disclose the data to the extent provided in the resulting contract. This restriction does not limit PCORI’s right to use information contained in this data if it is obtained from another source without restriction. The data subject to this restriction are contained in sheets [insert numbers or other identification of sheets]”; and
- b) Mark each sheet of data it wishes to restrict with the following legend: “Use or disclosure of data contained on this sheet is subject to the restriction on the title page of this proposal.”

**Rights in Data—General**

If applicable, insert the following terms and/or conditions with any appropriate alternates:

**1.0 Definitions**

As used in this procurement effort and with respect to data, information and technology integrity—

Term	Definition/Meaning
Computer database or database	A collection of recorded information in a form capable of, and for the purpose of, being stored in, processed, and operated on by a computer. The term does not include computer software.
Computer software	(i) Computer programs that comprise a series of instructions, rules, routines, or statements, regardless of the media in which recorded, that allow or cause a computer to perform a specific operation or series of operations; and  (ii) Recorded information comprising source code listings, design details, algorithms, processes, flow charts, formulas, and related material that would enable the computer program to be produced, created, or compiled.  Note: Does not include computer databases or computer software documentation.
Computer software documentation	Owner’s manuals, user’s manuals, installation instructions, operating instructions, and other similar items, regardless of storage medium, that explain the capabilities of the computer software or provide instructions for using the software.
Data	Recorded information, regardless of form or the media on which it may be recorded. The term includes technical data and computer software. The term does not include information incidental to contract administration, such as financial, administrative, cost or pricing, or management information.
Form, fit, and function	Data relating to items, components, or processes that are sufficient to enable

data	physical and functional interchangeability, and data identifying source, size, configuration, mating and attachment characteristics, functional characteristics, and performance requirements. For computer software it means data identifying source, functional characteristics, and performance requirements but specifically excludes the source code, algorithms, processes, formulas, and flow charts of the software.
Limited rights	The rights of PCORI in limited rights data as set forth in the Limited Rights Notice, if included. (See end of section.)
Limited rights data	Data, other than computer software, that embody trade secrets or are commercial or financial and confidential or privileged, to the extent that such data pertain to items, components, or processes developed at private expense, including minor modifications.
Restricted computer software	Computer software developed at private expense and that is a trade secret, is commercial or financial, and confidential or privileged, or is copyrighted computer software, including minor modifications of the computer software.
Restricted rights	The rights of the Government in restricted computer software, as set forth in a Restricted Rights Notice of paragraph (g) if included in this clause, or as otherwise may be provided in a collateral agreement incorporated in and made part of this contract, including minor modifications of such computer software.
Technical data	Recorded information (regardless of the form or method of the recording) of a scientific or technical nature (including computer databases and computer software documentation). This term does not include computer software or financial, administrative, cost or pricing, or management data or other information incidental to contract administration. The term includes recorded information of a scientific or technical nature that is included in computer databases.
Unlimited rights	The rights of PCORI to use, disclose, reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, in any manner and for any purpose, and to have or permit others to do so.

## 2.0 Allocation of Rights

- 2.1 Unless specifically noted, PCORI shall have unlimited rights in:
- 2.1.1 Data first produced in the performance of this contract;
  - 2.1.2 Form, fit, and function data delivered under this contract;
  - 2.1.3 Data delivered under this contract (except for restricted computer software) that constitute manuals or instructional and training material for installation, operation, or routine maintenance and repair of items, components, or processes delivered or furnished for use under this contract; and
  - 2.1.4 All other data delivered under this contract unless provided otherwise for limited rights data or restricted computer software.
- 2.2 The Contractor shall have the right to:
- 2.2.1 Assert copyright in data first produced in the performance of this contract;
  - 2.2.2 Use, release to others, reproduce, distribute, or publish any data first produced or specifically used by the Contractor in the performance of this contract;
  - 2.2.3 Substantiate the use of, add, or correct limited rights, restricted rights, or copyright notices and to take other appropriate action; and

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2.2.4 Protect from unauthorized disclosure and use those data that are limited rights data or restricted computer software to the extent provided in paragraph (g) of this clause.

2.3 Copyright:

2.3.1 Data first produced in the performance of this contract.

2.3.2 Unless provided otherwise in paragraph (d) of this clause, the Contractor may, without prior approval of the Contracting Officer, assert copyright in scientific and technical articles based on or containing data first produced in the performance of this contract and published in academic, technical, or professional journals; symposia proceedings; or similar works. The prior, express written permission of the Contracting Officer is required to assert copyright in all other data first produced in the performance of this contract.

2.3.3 When authorized to assert copyright to the data, the Contractor shall affix the applicable copyright notices of [17 U.S.C. 401 or 402](#) and an acknowledgment of sponsorship (including contract number).

2.3.4 For data other than computer software, the Contractor grants to PCORI, and others acting on its behalf, a paid-up, nonexclusive, irrevocable, worldwide license in such copyrighted data to reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly by or on behalf of PCORI. For computer software, the Contractor grants to PCORI, and others acting on its behalf, a paid-up, nonexclusive, irrevocable, worldwide license in such copyrighted computer software to reproduce, prepare derivative works, and perform publicly and display publicly (but not to distribute copies to the public) by or on behalf of PCORI.

2.3.4.1 Data not first produced in the performance of this contract. The Contractor shall not, without the prior written permission of the Contracts Department, incorporate in data delivered under this contract any data not first produced in the performance of this contract unless the Contractor:

- Identifies the data; and
- Grants to PCORI, or acquires on its behalf, a license of the same scope as set forth in paragraph 2.3.1, or, if such data are restricted computer software, PCORI shall acquire a copyright license (if included in this contract) or as otherwise provided in a collateral agreement incorporated in or made part of this contract.

2.3.4.2 Removal of copyright notices. PCORI will not remove any authorized copyright notices placed on data pursuant to this paragraph 2.3 and will include such notices on all reproductions of the data.

2.3.4.3 Release, publication, and use of data. The Contractor shall have the right to use, release to others, reproduce, distribute, or publish any data first produced or specifically used by the Contractor in the performance of this contract, except:

- As prohibited by Federal law or regulation (eg, export control or national security laws or regulations);
- As expressly set forth in this contract; or
- If the Contractor receives or is given access to data necessary for the performance of this contract that contain restrictive markings, the

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Contractor shall treat the data in accordance with such markings unless specifically authorized otherwise in writing by the Contracts Department.

2.3.5 Unauthorized marking of data.

2.3.5.1 Notwithstanding any other provisions of this contract concerning inspection or acceptance, if any data delivered under this contract are marked with the notices specified in paragraph "Limited Rights Notice," if included, and use of the notices is not authorized, or if the data bears any other restrictive or limiting markings not authorized by this contract, the Contracts Department may at any time either return the data to the Contractor, or cancel or ignore the markings. However, pursuant to [41 U.S.C. 253d](#), the following procedures shall apply prior to canceling or ignoring the markings.

2.3.5.1.1 The Contracts Department will make written inquiry to the Contractor affording the Contractor 60 days from receipt of the inquiry to provide written justification to substantiate the propriety of the markings;

2.3.5.1.2 If the Contractor fails to respond or fails to provide written justification to substantiate the propriety of the markings within the 60-day period (or a longer time approved in writing by the Contracts Department for good cause shown), PCORI shall have the right to cancel or ignore the markings at any time after said period and the data will no longer be made subject to any disclosure prohibitions.

2.3.5.1.3 If the Contractor provides written justification to substantiate the propriety of the markings within the period set in paragraph 2.3.5.1.1 of this section, the Contracts Department will consider such written justification and determine whether or not the markings are to be cancelled or ignored. If the Contracts Department determines that the markings are authorized, the Contractor will be so notified in writing. If the Contracts Department determines, with concurrence of the head of the contracting activity, that the markings are not authorized, the Contracts Department will furnish the Contractor a written determination, which determination will become the final agency decision regarding the appropriateness of the markings unless the Contractor files suit in a court of competent jurisdiction within 90 days of receipt of the Contracting Officer's decision. The Government will continue to abide by the markings under this paragraph 2.3.5.1.1 until final resolution of the matter either by the Contracts Department's determination becoming final (in which instance PCORI will thereafter have the right to cancel or ignore the markings at any time and the data will no longer be made subject to any disclosure prohibitions), or by final disposition of the matter by court decision if suit is filed.

2.3.5.2 Except to the extent PCORI's action occurs as the result of final disposition of the matter by a court of competent jurisdiction, the Contractor is not precluded by paragraph 2.3.5 of this section from bringing a claim that may

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arise as the result of PCORI removing or ignoring authorized markings on data delivered under this contract.

2.3.6 Omitted or incorrect markings.

2.3.6.1 Data delivered to PCORI without any restrictive markings shall be deemed to have been furnished with unlimited rights. PCORI is not liable for the disclosure, use, or reproduction of such data.

2.3.6.2 If the unmarked data has not been disclosed without restriction outside PCORI, the Contractor may request, within six months (or a longer time approved by the Contracts Department in writing for good cause shown) after delivery of the data, permission to have authorized notices placed on the data at the Contractor's expense. The Contracting Officer may agree to do so if the Contractor:

2.3.6.2.1 Identifies the data to which the omitted notice is to be applied;

2.3.6.2.2 Demonstrates that the omission of the notice was inadvertent;

2.3.6.2.3 Establishes that the proposed notice is authorized; and

2.3.6.2.4 Acknowledges that PCORI has no liability for the disclosure, use, or reproduction of any data made prior to the addition of the notice or resulting from the omission of the notice.

2.3.6.3 If data has been marked with an incorrect notice, the Contracts Department may:

2.3.6.3.1 Permit correction of the notice at the Contractor's expense if the Contractor identifies the data and demonstrates that the correct notice is authorized; or

2.3.6.3.2 Correct any incorrect notices.

2.3.7 Protection of limited rights data and restricted computer software.

2.3.7.1 The Contractor may withhold from delivery qualifying limited rights data or restricted computer software that are not data identified in paragraphs 2.1.1, 2.1.2, and 2.1.3 of this section. As a condition to this withholding, the Contractor shall:

2.3.7.1.1 Identify the data being withheld; and

2.3.7.1.2 Furnish form, fit, and function data instead.

2.3.7.2 Limited rights data that are formatted as a computer database for delivery to PCORI shall be treated as limited rights data and not restricted computer software.

2.3.8 Subcontracting. The Contractor shall obtain from its subcontractors all data and rights therein necessary to fulfill the Contractor's obligations to PCORI under this contract. If a subcontractor refuses to accept terms affording PCORI those rights, the Contractor shall promptly notify the Contracts Department of the refusal and shall not proceed with the subcontract award without authorization in writing from the Contracts Department.

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- 2.3.9 Relationship to patents or other rights. Nothing contained in this section shall imply a license to PCORI under any patent or be construed as affecting the scope of any license or other right otherwise granted to PCORI.

**LIMITED RIGHTS NOTICE (Optional)**

These data are submitted with limited rights under Contract No. \_\_\_\_\_ and, if applicable, Subcontract No. \_\_\_\_\_. These data may be reproduced and used by the Company and PCORI with the express limitation that they will not, without written permission of the Seller, be used for purposes of manufacture nor disclosed outside the Company or PCORI; except that the Company and PCORI may disclose these data outside the Company and PCORI for the following purposes, if any; provided that the Company or PCORI makes such disclosure subject to prohibition against further use and disclosure:

- a) Use (except for manufacture) by support service contractors or subcontractors.
- b) Evaluation by PCORI contracted evaluators.
- c) Use (except for manufacture) by other contractors or subcontractors participating in PCORI's program of which the specific subcontract is a part.
- d) Emergency repair or overhaul work.

This Notice shall be marked on any reproduction of these data, in whole or in part.