Request for Proposal (RFP)

PCORI

Results Analysis Services
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SECTION 1  THE SCHEDULE

RESULTS ANALYSIS SERVICES
RFP #PCO-ANLYS2012
Request for Proposal (RFP)

1.0  Background

The Patient-Centered Outcomes Research Institute (PCORI) is an independent, nonprofit research organization created by the Patient Protection and Affordable Care Act of 2010. The mission of PCORI is to help people make better-informed healthcare decisions—and improve healthcare delivery and outcomes—by producing and promoting high-integrity, evidence-based information derived from research guided by patients, caregivers, and the broader healthcare community. Research commissioned by PCORI aims to be responsive to the values and interests of patients and to provide patients and those who care for them with reliable, evidence-based information for the healthcare choices they face.

Patient-centered outcomes research (PCOR) helps people and their caregivers communicate and make informed healthcare decisions, allowing their voices to be heard in assessing the value of healthcare options. This research answers patient-centered questions such as:

1. “Given my personal characteristics, conditions, and preferences, what should I expect will happen to me?”
2. “What are my options, and what are the potential benefits and harms of those options?”
3. “What can I do to improve the outcomes that are most important to me?”
4. “How can clinicians and the care delivery systems they work in help me make the best decisions about my health and health care?”

In May 2012, the PCORI Methodology Committee delivered the Draft Methodology Report and Methods Standards (“the Report”) to the PCORI Board of Governors, in accordance with PCORI’s enabling legislation. PCORI will solicit public input on the Report during a public comment period of between 45 and 60 days, with a primary goal of enabling the Methodology Committee to be responsive to public input and to create a revised version of the Report for PCORI Board of Governors approval at their meeting in November 2012.

2.0  Description

PCORI seeks a Contractor who can provide services in the area of analyzing results from public comment periods.

3.0  Pricing Requirements

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

<table>
<thead>
<tr>
<th>Line Item</th>
<th>Results Analysis Services</th>
<th>Type</th>
<th>Quantity</th>
<th>Hours</th>
<th>Unit Price</th>
<th>Pricing</th>
</tr>
</thead>
<tbody>
<tr>
<td>0001</td>
<td>Labor Mix</td>
<td>FFP</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Travel²</td>
<td>Cost Reimbursable</td>
<td>NTE</td>
<td>$5,000</td>
<td></td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>---------</td>
<td>------------------</td>
<td>-----</td>
<td>--------</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note 1: See Section 2, paragraph 2.4 for directions on staffing.
Note 2: Travel expenses will be reimbursed. Anticipated travel is one day for three people at a Not-to-Exceed rate of $5,000.
SECTION 2 PERFORMANCE WORK STATEMENT (PWS)

RFP #PCO-ANLYS2012
SCHEDULE OF SUPPLIES/SERVICES

1.0 Scope of Work

1.1 The Contractor shall provide result analysis services for the public comment period. For the public comment period for the Report, PCORI will actively solicit input from researchers, but a key element of the public comment period is also soliciting input from non-researchers on the content of the Report. PCORI will specifically contract for the analysis of the non-researcher comments. This analysis will take place in parallel to and coordinated with the analysis of the researcher comments by another vendor. Non-researcher input is critical, both to communicate PCORI's commitment to engaging the public in all of its scientific endeavors, but also to ensure that input received can improve the quality and usefulness of the Report, not just for the research community but for every other stakeholder group that may be involved in PCORI-funded work and/or that may apply for PCORI funding.

1.2 Collection of public comment on Methodology Report. See paragraph 2.0.

1.3 Statement of Objectives for Final Report. PCORI is committed to ensuring wide access to PCORI products. Following public posting of the Methodology Committee Report, a public comment period will be held to solicit feedback from researchers, patients, and other stakeholders. This RFP is for the analysis of patient and other non-researcher stakeholder comment on the Report. The Contractor should indicate all details of the plan to analyze and report results and to provide the Methodology Committee with specific feedback useful for future revisions of the Report.

1.4 The Contractor’s specific responsibilities will include thoroughly reviewing the Report, ensuring comprehensive understanding of the contents through additional reading as needed of Report source documents, including Contractor reports and other sources. Discussion with PCORI staff about content is required to ensure adequate understanding for drafting survey input items.

2.0 Contractor Requirements for Providing Results Analysis Services

2.1 Manage Public Comment Input

2.1.1 Provide plan for ongoing monitoring of input from a public comment collection tool, e-mail, and paper mail. Work with existing team to receive data from established public comment tool. Describe process for monitoring and reporting on responses in “real time” with a frequency of no less than once a week during the remainder of the anticipated 60-day public comment period. Develop a plan to forward appropriate comments in “real time” to the technical comment review team.

2.2 Complete Analysis and Create Final Report

2.2.1 Create analysis plan for all non-researcher input obtained. Coordinate analysis with team responsible for researcher public comment. Describe planned format for summarizing data and communicating input received to PCORI staff, Methodology Committee, Board of Governors, and the public. Consider differentiated results communication plans, stratified by audience.
2.3 Support of Methodology Report

2.3.1 Make available relevant staff to respond to questions about the non-researcher comment outcomes from the Methodology Committee writing team. Also, prepare a U.S. Government Accountability Office (GAO) audit compliance package, documenting and archiving all data collected, analysis method, disposition method, and overall processes and work plan.

2.4 Project Management

The Contractor shall provide personnel, equipment, or technology necessary to assure that the highest quality of service is provided. The Contractor shall have the capability to provide a professional analysis and requested reports. 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.

2.4.1 Key Personnel

2.4.1.1 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 analysis, collection, and reporting services and shall have adequate authority to make decisions for the timely resolution of problems. The Project Manager shall coordinate closely with the Engagement Research Directorate.

2.4.1.2 Throughout the duration of the contract, the Contractor is required to attend weekly calls with PCORI staff to provide updates of progress.

2.4.1.3 The Contractor will be required to present to PCORI staff in Washington, D.C., in September 2012, prior to completion of analysis of input.

2.4.2 Other Staff/Subcontractors

The Contractor shall propose how it will staff the results analysis project to support PCORI’s needs to include all services described in this scope of work. The Contractor shall briefly describe the staff members required, their roles in this effort, and their backgrounds and education. 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 anticipated.

4.0 Furnishing of Equipment/Property

PCORI will furnish information, but the Contractor shall furnish its own office, equipment, personnel, and technology.

5.0 Period of Performance

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

Project-based 30 July 2012 – 15 October 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 quality controls it has in place will meet the requirements of the performance of this contract.

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.

<table>
<thead>
<tr>
<th>Quality Measurement</th>
<th>Quality Level</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exceeds</td>
</tr>
<tr>
<td>Responding to Inquiries/Calls</td>
<td>Responds same day</td>
</tr>
<tr>
<td>Final Report</td>
<td>Plain language, readable, well organized, comprehensive capture of all themes, and informed prioritizing of issues to address in MC* Report revision process</td>
</tr>
</tbody>
</table>

* Methodology Committee

7.0 **Deliverables**

The Contractor shall provide the following deliverables/submittals within the time frames identified below:
<table>
<thead>
<tr>
<th>Deliverable</th>
<th>Due Date</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>First Draft of Analysis</td>
<td>13 August 2012</td>
<td>Send electronically to Director of Engagement Research</td>
</tr>
<tr>
<td>Complete Revisions</td>
<td>27 August 2012</td>
<td>Send electronically to Director of Engagement Research</td>
</tr>
<tr>
<td>Final Report Phase 2</td>
<td>28 September 2012</td>
<td>Send electronically to Director of Engagement Research</td>
</tr>
<tr>
<td></td>
<td>(public comment closes 14 Sep 2012)</td>
<td></td>
</tr>
<tr>
<td>Teleconference with Methodology Writing Team</td>
<td>1 October 2012</td>
<td>Send electronically to Director of Engagement Research</td>
</tr>
<tr>
<td>Draft Compliance Package</td>
<td>8 October 2012</td>
<td>Send electronically to Director of Engagement Research</td>
</tr>
<tr>
<td>Final Compliance Package</td>
<td>15 October 2012</td>
<td>Send electronically to Director of Engagement Research</td>
</tr>
<tr>
<td>Ad-hoc</td>
<td></td>
<td>Send electronically to Director of Engagement Research</td>
</tr>
</tbody>
</table>

**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.

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

- **First Analysis Draft and Revisions:** Outline listing all key themes with suggestions for ordering of themes and suggestions for prioritizing issues for the Methodology Committee to discuss during the Report revision process.

- **Final Report Phase 2:** Report (up to 25 pages) detailing all themes that were expressed in comments, with both text and graphical representation of comment contents grouped by theme and with reference to low-frequency themes, along with detailed suggestions for the Methodology Committee on addressing elements from the comments in the MC Report revision.

- **Draft and Final Compliance Packages:** Process document (up to five pages) detailing processes for future GAO audit and electronic files of any annotations of comments or documents used for decision making.

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 personnel, equipment, technology, and office space 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 0900 and 1730 hours 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 contract falls under Simplified Acquisition Procedures and its monetary thresholds, which are designed to reduce administrative costs; improve opportunities for small businesses; promote efficiency and economy in contracting; and avoid unnecessary burdens for PCORI and the respondents.

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

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.
SECTION 3  SOLICITATION PROVISIONS

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 and the Offeror’s understanding of the project. The submission shall be no longer than 10 pages.

1.4  Management Approach. The Offeror shall demonstrate that it has the ability to manage and control the project to ensure successful 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. Results Analysis Services for the events described in Section 1.0, paragraph 3.0. The Offeror should describe each cost line item number:

1.6.1  Item 0001: Firm Fixed Price

1.6.2  Item 0002: Cost Reimbursable for Travel

1.7  Questions to be addressed and submitted to rfp@pcori.org with reference to the solicitation number in the subject line due by close of business July 2, 2012.

1.8  E-mail proposal responses to rfp@pcori.org with reference to the solicitation number in the subject line due by 1700ET, July 10, 2012.
1.9 Anticipated award date for proposal: July 18, 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 following 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

<table>
<thead>
<tr>
<th>Transaction Description</th>
<th>Weight of Rating Factor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technical Proposal</td>
<td>40%</td>
</tr>
<tr>
<td>Management Approach</td>
<td>25%</td>
</tr>
<tr>
<td>Past Performance</td>
<td>25%</td>
</tr>
<tr>
<td>Cost Proposal</td>
<td>10%</td>
</tr>
</tbody>
</table>

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 and within the competitive range to conduct a presentation to PCORI on the proposed effort for technical
and management approaches 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 or mailed to:

PCORI
Att: 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 seven 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:

<table>
<thead>
<tr>
<th>Type of Insurance</th>
<th>Limits of Liability</th>
</tr>
</thead>
<tbody>
<tr>
<td>General Liability</td>
<td>$1,000,000</td>
</tr>
</tbody>
</table>

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 10 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 project based effort from 27 July 2012 – 15 October 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
PCORI prefers electronic means of invoicing. Invoices shall be provided to the Finance Department at:

- Every 30 days
- Progress Payments based on Deliverables/Milestones

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

E-mail: finance@pcori.org

7.0 **Refund Procedures**

Not applicable.
<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Business Day</td>
<td>Monday through Friday, 0900 – 1730 hours</td>
</tr>
<tr>
<td>FD</td>
<td>Finance Department</td>
</tr>
<tr>
<td>PCORI</td>
<td>Patient-Centered Outcomes Research Institute</td>
</tr>
<tr>
<td>POC</td>
<td>Point of Contact</td>
</tr>
<tr>
<td>PWS</td>
<td>Performance Work Statement</td>
</tr>
<tr>
<td>QASP</td>
<td>Quality Assurance Surveillance Plan; intended to ensure the qualitative success of the performance of the contract with measurements and monitoring by PCORI</td>
</tr>
<tr>
<td>Section 508</td>
<td>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></td>
</tr>
<tr>
<td>SLA</td>
<td>Service Level Agreement; a binding agreement for the level of service or quality of performance the Contractor commits to PCORI</td>
</tr>
</tbody>
</table>
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—

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition/meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>Computer database or database</td>
<td>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.</td>
</tr>
</tbody>
</table>
| 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                                                                                                                                 |

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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
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 (e.g., 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
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
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:

- Identifies the data to which the omitted notice is to be applied;
- Demonstrates that the omission of the notice was inadvertent;
- Establishes that the proposed notice is authorized; and
- 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:

- 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
- 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:

- Identify the data being withheld; and
- 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.
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.