Winter 2014 Funding Cycle*

PCORI Application Guidelines: Improving Methods for Conducting Patient-Centered Outcomes Research

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These guidelines apply to the Winter 2014 Funding Cycle for the PCORI Funding Announcement for Improving Methods for Conducting Patient-Centered Outcomes Research. The funding announcement, templates, and other resources are available at pcori.org/methods. The Winter 2014 Funding Cycle closes January 21, 2013.

* Previously released as the December 2013 Funding Cycle
*This version replaces the version posted September 27, 2013.
About PCORI

PCORI is committed to transparency and a rigorous stakeholder-driven process that emphasizes patient engagement. PCORI uses a variety of forums and public comment periods to obtain public input to enhance its work. PCORI helps people make informed healthcare decisions and improves healthcare delivery and outcomes by producing and promoting high-integrity, evidence-based information that comes from research guided by patients, caregivers, and the broader healthcare community.

PCORI was authorized by the Patient Protection and Affordable Care Act of 2010 as a non-profit, nongovernmental organization. PCORI’s purpose, as defined by the law, is to help patients, clinicians, purchasers, and policy makers make better informed health decisions by “advancing the quality and relevance of evidence about how to prevent, diagnose, treat, monitor, and manage diseases, disorders, and other health conditions.”

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Follow us on Twitter: @PCOR
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1.0 About These Guidelines

This document provides key information to help researchers prepare respond to the PCORI Funding Announcement (PFA) for Improving Methods for Conducting Patient-Centered Outcomes Research. Researchers wishing to respond to other PCORI funding announcements can find related information at pcori.org/PFA/apply.

These guidelines may answer many questions you might have, but other resources are also available. PCORI’s Applicant FAQs¹ cover common questions about PCORI and the application process. These are updated on a regular basis to reflect questions received through our helpdesk and applicant town halls.

For programmatic questions, please email (pfa@pcori.org), phone (202-627-1884), or contact us online² if you have any questions regarding this PCORI Funding Announcement or would like to schedule a call with program staff. PCORI will provide a response within 72 hours. However, PCORI cannot guarantee that all questions will be addressed 72 hours prior to a Letter of Interest or application deadline.

For administrative, financial, or technical questions, please e-mail pfa@pcori.org. PCORI will respond within 48 hours. Of note, during the week of the application due date, response times may exceed 48 hours. The applicants are advised to plan accordingly. It is the applicant’s responsibility to submit the application on or before the deadline.

To review PCORI’s funded contract terms and conditions, see PCORI Contract for Funded Research Projects.³

2.0 Who Can Apply

Applications may be submitted by any private sector research organization, including any non-profit or for-profit organization; any public sector research organization, including any university or college hospital or healthcare system, laboratory or manufacturer, unit of state or local government. All US applicant organizations must be recognized by the Internal Revenue Service. Non-domestic components of organizations based in the United States and foreign organizations may apply, as long as there is demonstrable benefit to the US healthcare system and US efforts in the area of patient-centered research can be clearly shown. Organizations may submit multiple applications for funding. Individuals are not permitted to apply.

¹ Available at http://pcori.org/funding-opportunities/applicant-faqs
² Available at http://www.pcori.org/PFA/inquiry
³ Available at http://pcori.org/assets/2013/09/PCORI-PFA-Contract-for-Funded-Research-Projects.pdf
3.1 How to Apply

Applicants must follow all technical and administrative directions provided in these guidelines and within the PCORI Online System. All required documents must be uploaded as PDF documents into the PCORI Online System. Failure to submit all required documents into the PCORI Online System may result in removal of the application from the review process.

Step 1: Register

To apply for PCORI funding, you must register in the PCORI Online System. Your name, an email, a password, and a security question and answer are required to register. The email entered will be your username.

Step 2: Provide a Letter of Intent (LOI)

Provide a Letter of Intent by completing the required fields in the PCORI Online System. A Letter of Intent must be submitted prior to completion of an application. A Letter of Intent is also required for resubmitted applications. Upon receipt, PCORI program staff will screen Letters of Intent for programmatic fit. An applicant whose Letter of Intent does not meet program areas of interest will not be invited to submit a full application. PCORI encourages prospective applicants to contact us with questions prior to the deadline.

Step 3: Apply

Use the left navigation within the PCORI Online System to enter required information. Note that there are seven sections to the application. Use the left side navigation to navigate to any section at any time. You can return to complete your application as many times as needed. However, you must go to the Save and Review section and click the “Save and Review” button to save your work before exiting.

Step 4: Upload Required Documents

PCORI provides required templates for several components. Templates can be downloaded from the PCORI Funding Center and completed following the instructions provided in these guidelines. You may delete any text within a template that is not applicable to your application. Letters of Support must be provided in the format listed below, combined and saved into one PDF, and uploaded to the PCORI Online System:

- **Header:** Each page should include the full name of the PI in the page header’s left corner.

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4 Available at contracts1.pcori.org
5 Available at pcori.org/apply
Margins: Use half-inch margins or greater. The header may fall within the top margin, but the body text should not begin closer than one half-inch from the edge of the page.

Font: Use size 11 Arial or Times New Roman font for the main body of the text. Figures and captions may have smaller type.

Page Numbering: Number each page of the document consecutively.

Spacing: Use single spacing.

Document Format: All uploaded documents must be in PDF format.

Also refer to specific instructions for each application component that are provided below and in required templates, where applicable.

Step 5: Submit for Authorization

After all required information has been entered and all required documents have been uploaded, click “Submit” to forward the application to your administrative official (AO) to authorize. The PI and the AO may not be the same individual. Only the AO may approve the final application. Please ensure that the AO approves and submits the application to PCORI prior to the submission deadline. Following the submission of an application, you will receive an email confirmation.

4.0 When to Apply

Application deadlines for each PCORI funding cycle are noted in the PCORI Funding Center and on PCORI funding announcements. Deadlines are at 5:00 PM ET on the due date noted. If deadlines fall on a weekend or a federal holiday, the deadline will be the following Monday or the next day after the federal holiday.

PCORI Online System issues that threaten the on-time submission of an application must be reported to PCORI prior to the stated due date and time. PCORI will investigate reports of system issues on a case-by-case basis. PCORI reserves the right to extend the application due date and time due to such issues. Problems with computer systems at the applicant organization, failure to follow instructions in PCORI Online System, these guidelines, or a PCORI funding announcement, or failure to complete all required registrations by the submission deadline are not considered system issues.

5.0 What to Include

Required and optional application components, the submission method, and the maximum length or limit are noted below. There are two submission methods: (1) Applicants enter information into fields in the PCORI Online System or (2) Applicants complete and upload required templates. Templates can be downloaded from the PCORI Funding Center or from links included on the following page.
### PCORI December 2013 Cycle Funding Announcement: Checklist and Links to Improving Methods

#### Application Components

<table>
<thead>
<tr>
<th>Application Section/Component</th>
<th>Submission Method</th>
<th>Length/Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Letter of Intent</td>
<td>Enter into PCORI Online System</td>
<td>N/A</td>
</tr>
<tr>
<td>• Technical Abstract Worksheet</td>
<td>Copy and paste text from worksheet into PCORI Online System</td>
<td>3,000 characters/spaces</td>
</tr>
<tr>
<td>• Greater Than 750K Template (if applicable)</td>
<td>Upload template saved as PDF</td>
<td>As noted in template</td>
</tr>
<tr>
<td>PI and Contact Information</td>
<td>Enter into PCORI Online System</td>
<td>N/A</td>
</tr>
<tr>
<td>Project Information</td>
<td>Enter into PCORI Online System</td>
<td>As noted below</td>
</tr>
<tr>
<td>• Resubmission</td>
<td>Select Yes or No</td>
<td>N/A</td>
</tr>
<tr>
<td>• Technical Abstract</td>
<td></td>
<td>3,000 characters/spaces</td>
</tr>
<tr>
<td>• Narratives</td>
<td></td>
<td>1,000 characters/spaces each</td>
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<tr>
<td>• Specific Aims</td>
<td></td>
<td>3,000 characters/spaces</td>
</tr>
<tr>
<td>• Public Abstract</td>
<td></td>
<td>3,000 characters/spaces</td>
</tr>
<tr>
<td>Key Personnel</td>
<td>Enter into PCORI Online System</td>
<td>As needed</td>
</tr>
<tr>
<td>Budget Summary</td>
<td>Enter into PCORI Online System</td>
<td>As required</td>
</tr>
<tr>
<td>Milestones</td>
<td>Enter into PCORI Online System</td>
<td>As needed</td>
</tr>
<tr>
<td>Research Plan Template</td>
<td>Upload template saved as PDF</td>
<td>As noted below</td>
</tr>
<tr>
<td>• Research Strategy</td>
<td></td>
<td>15 pages</td>
</tr>
<tr>
<td>• Dissemination and Implementation Potential</td>
<td></td>
<td>2 pages</td>
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<tr>
<td>• Reproducibility and Transparency of Research</td>
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<td>2 pages</td>
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<tr>
<td>• Protection of Human Subjects</td>
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<td>5 pages</td>
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<tr>
<td>• References Cited</td>
<td></td>
<td>10 pages</td>
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<tr>
<td>• Consortium Contractual Arrangements</td>
<td></td>
<td>5 pages</td>
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<tr>
<td>• Appendix (optional)</td>
<td></td>
<td>10 pages</td>
</tr>
<tr>
<td>People and Places Template</td>
<td>Upload template saved as PDF</td>
<td>As noted below</td>
</tr>
</tbody>
</table>
See below for instructions that you should keep in mind for each component.

**Letter of Intent**

Enter information in the required fields in the PCORI Online System. This must be submitted prior to completion of an application. You may use the Letter of Intent Technical Abstract Worksheet\(^6\) to develop this section.

Note that, under this priority area for funding, PCORI aims to fund projects for three years, with budgets up to $750,000 of Total Direct Costs over the life of the project. However, PCORI is willing to consider projects that exceed either or both of these stipulations, provided permission is granted from PCORI.

Note that although both subcontractor direct and indirect costs are considered to be direct costs to the prime, subcontractor indirect costs should not be included when determining if the budget exceeds the $750,000 limit.

To request permission, you must complete and submit a Greater Than $750K Template\(^7\). Include a clear explanation of why your budget and/or project duration exceeds the limit. You may be contacted for additional information.

While PCORI will convene promptly to discuss all submitted requests, the decision-making process may require additional time or information, which may postpone submission of an application until a subsequent application cycle. Applicants will be notified by e-mail of an approval/denial decision two weeks after the LOI due date. If the request to exceed the PCORI budget limit was not approved at the LOI stage, the application will not be reviewed if submitted. PCORI will administratively triage any application that includes a budget greater than $750,000 of Total Direct Costs over the life of the project and/or any application with a project period exceeding three years if permission is not requested from PCORI prior to the submission of an application.

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PI and Contact Information

This is a section within the PCORI Online System. Review and edit, if necessary, information about the primary PI carried over from your LOI. PCORI refers to three specific roles with particular responsibilities (see below). Keep the following in mind as you complete this section:

Principal Investigator (PI)
A. Description
   - Responsible for scientific or technical aspects
   - Applications can include multiple Co-PIs
   - Applicants must designate one PI as a primary contact.
   - The PI’s institution must be the primary institution for the award
   - Investigators may serve as PI on only one application per cycle for any individual PCORI PFA
   - PIs can participate in other applications (from the same or other organizations) in a different role, such as co-investigator or consultant
   - PCORI is committed to identifying and funding new investigators who show exceptional promise for conducting research that addresses methodological gaps in patient-centered outcomes research. Beginning with the December 2013 Funding Cycle, we plan to fund a yet-to-be-determined number of meritorious applications submitted by principal investigators who have completed their terminal research degree or medical residency no more than seven years before the application deadline.

B. Activities
   - Assume responsibility and accountability for research execution, organization conduct, and compliance
   - Day-to-day management of the research and project
   - Lead research representative of the organization/ institution
   - Serve as PCORI lead point of contact

Administrative Official (AO)
A. Description
   - Responsible for matters related to the award and administration of the contract
   - The AO must not also be the PI
   - The AO’s signature certifies that the organization/institution will be accountable for both the appropriate use of funds awarded and for the performance of the PCORI-supported project or activities resulting from the application

B. Activities
   - Management of the contract activation, renewals, milestones, and additional materials required
• Oversee submission of the contract activation, renewals, milestones, and additional materials required
• Certify contract compliance of all applicable assurances and certifications referenced in the application

Financial Official (FO)
A. Description
    • Responsible for required annual expenditure reports

B. Activities
    • Complete and certify the required yearly expenditure reports
    • Execute accounting of contract funds and submission of invoices and payment details

Resubmission

PCORI receives hundreds of applications for PFA each cycle. Funding on the first attempt is difficult, but not impossible. If an application does not result in funding, a PI or organization may resubmit an application for a specific PFA. We do not limit the number of resubmissions, however applicants wishing to reapply must submit a new Letter of Intent.

If you are resubmitting an application, you are strongly encouraged to address all the reviewers’ critiques within the Research Strategy section of the Research Plan by adding a section prior to Part A. The page limits of the Research Plan can be exceeded by five pages (not to exceed 20 pages total) if additional space is needed. If you choose to respond in a different approach, such as responding to comments throughout the research plan, please bold and footnote changes to explain how you have addressed previous reviewer critiques.

To indicate that your application is a resubmission, please select the appropriate drop-down in the “Resubmission” field on the “Project Information” page, click the “Select” button, and enter the ID from your original application.

Technical Abstract

Enter information in the PCORI Online System. Provide a thorough description that allows the scientific community to understand the project, including the aims and study design, without reviewing the full application. Your technical abstract must include the following sections:

• Background—state the problem or question your research is designed to address.
• Objectives—describe briefly the specific aims of the study, including specific research question(s) and the long-term objectives.
• Methods—give a concise description of the study population, sample size, and analytic methods that will be employed. Your proposed research is required to adhere to all relevant PCORI Methodology Standards.  

• Patient Outcomes—specify the study outcomes and state briefly why these are important to patients.

Narratives

Enter information in the PCORI Online System. Describe how your research plan is responsive to the specific PFA you are applying for; how this research is comparative, name the comparators, and why the comparison is important (please note that only clinical comparative effectiveness research is funded by PCORI); and briefly summarize your patient engagement plan.

Specific Aims

Enter information in the PCORI Online System. Provide the overall goals of your proposed research. Describe the study design and the research questions (hypotheses), including:

• The comparisons to be evaluated.
• The outcomes that will be studied.
• The anticipated impact of study results on clinical or patient decision making and on patient outcomes.

Public Abstract

Enter information in the PCORI Online System. Provide a thorough description, written in lay language, that allows the general public to understand your project without reviewing the full application. The public abstract will be published on PCORI’s website. The public abstract must include the same basic information as in the technical abstract. You will need to summarize your project’s potential impact along with the comparators in your research project. You will also need to summarize how you will engage patients and stakeholders in your research.

Key Personnel

Enter information in the PCORI Online System. Keep the following guidelines in mind as you complete this section:

• Applications can include multiple Co-PIs
• PIs can serve in other applications as other roles (co-investigator or consultant)
• Individuals cannot serve as PIs for multiple PCORI Funding Awards in the same cycle

8 Available at www.pcori.org/assets/PCORI-Methodology-Standards1.pdf
• Investigators may serve as PI on only one application per cycle for any individual PCORI PFA. An individual who is a PI may, however, participate in other applications (from the same or other organizations) in a different role, such as co-investigator or consultant.
• The AO must not also be the PI
• The AO’s signature certifies that the organization/institution will be accountable for both the appropriate use of funds awarded and for the performance of the PCORI-supported project or activities resulting from the application

Budget Summary

Complete the Budget Summary section in the PCORI Online System. Your budget summary should reflect all costs for the entire proposed project period. See Appendix 2: Allowable and Unallowable Costs to review acceptable and unacceptable uses of PCORI contract funds.

Milestones

Enter information in the PCORI Online System. Milestones are concrete, specific events or accomplishments that are documented by deliverables. They should include only activities that are supported by the PCORI contract. Examples of milestones include: minutes of major meetings of the research partners (scientists and patient/stakeholder representatives), recruitment of patients or research subjects, survey development, inception of the intervention, results of annual surveys of patient/stakeholder research partners, and establishment of databases. Exclude any PCORI reporting requirements, such as semi-annual progress or financial reports.

Your proposed research plan must include at least one deliverable or interim deliverable to be submitted to PCORI during each 12-month period of the project. This plan will be used to determine if project progress is appropriate to the timeline. These required deliverables will be included in your final agreement if your application is awarded a contract.

In addition to tracking these milestones, we are interested in learning how your work is having an impact. Therefore, should you be selected for a PCORI contract, the following additional deliverables may be required following contract execution:

• Abstracts from presentations made to professional groups or associations;
• Copies of papers accepted for publication;
• Copies of drafts of instruments, data dictionaries, educational materials, manuals, or other project deliverables;
• Reports of endorsement of research findings by scientific and consumer groups;
• Reports of plans to adopt research findings in practice;
• Charts, tables, graphs, or other summaries of preliminary data; and
• Other documents or materials as appropriate.
Research Strategy

This component is included in the Research Plan Template. The Research Strategy section aligns with PCORI’s five review criteria for Improving Methods for Conducting Patient-Centered Outcomes Research. Applications will be reviewed and scored against these criteria:

Criterion 1. Impact of the field of PCOR methods
Refers to the extent that the proposed methods are needed in the field of PCOR. The proposal addresses the following questions:
- How often would these methods be used, and how many PCOR studies would benefit from these improved methods?
- Do existing methods weaken the validity of PCOR studies, and would improved methods therefore increase the validity of PCOR findings?

Criterion 2. Potential for the study to improve PCOR methods
Refers to the potential of the proposed methodological investigation and its results to change methodological practices in ways that improve PCOR and the decisions made by patients. The proposal addresses the following questions:
- Does the research question address a critical gap in current methodological understanding as noted in the Methodology Committee Report or in other sources?
- Is the proposed approach feasible and likely to result in new standards or in the improvement of existing standards?

Criterion 3. Technical merit
Refers to the technical merit of the proposal. The proposal addresses the following questions:
- Is there a clear research plan with rigorous methods and key milestones clearly articulated?
- Do the study methods reflect state-of-the-art thinking and practice in the methodological area, so that results are likely to be accepted and heeded?
- Is the research team appropriately trained and experienced to carry out the planned studies?
- Is the research environment sufficient to support the conduct of the work, and are appropriate resources available?
- Will the proposed methods help support the inclusion and study of diverse populations with respect to age, gender, race, ethnicity, geography, or clinical status, or, alternatively, do the methods support the inclusion of previously understudied populations in PCOR?
Criterion 4. Patient-centeredness

Refers to the level of patient-centeredness of the proposal. The proposal addresses the following questions:

- Is the proposed methodological investigation specifically linked to improving PCOR methods, and specifically to the improved study of comparisons and patient-centered outcomes that are relevant and valued by patients, caregivers, and clinicians?
- For relevant studies, how credible are the application’s claims that engaged patients and stakeholders will exert meaningful influence on the design and conduct of the research, to ensure patient-centeredness of the questions and outcomes addressed?

Criterion 5: Patient and stakeholder engagement

Where applicable, proposals need to demonstrate patient and stakeholder engagement through the integration of patients and stakeholders in the development of the research plan and in key elements of the proposed project. The proposal addresses the following questions:

- Does the proposal describe how patients and stakeholders were or will be identified and engaged in the research and in formulation of research questions?
- What are the roles of patients and key stakeholders in formulating the study’s hypotheses and design and in the study’s conduct and dissemination of results, including defining essential characteristics of the study, participants, comparators, and outcomes?
- What roles do patients and stakeholders have in monitoring study conduct and progress?
- What roles do patients and stakeholders have in any planned dissemination or implementation plans?
- If the project has not included patient and stakeholder engagement (for example, in the area of analytic methods), has the application explained why it is not applicable and justified their non-inclusion?

Applications are considered non-responsive if research is proposed that:

- Conducts a formal cost-effectiveness analysis in the form of dollar-cost per quality-adjusted life-year (including non-adjusted life-years) to compare two or more alternatives
- Directly compares the costs of care between two or more alternative approaches as the criterion for choosing the preferred alternative

Dissemination and Implementation Potential

This component is included in the Research Plan Template. Describe the potential for disseminating and implementing the results of your work in other settings. PCORI does not expect you to undertake this work during the award period, if funded. For projects that produce important findings, PCORI will consider subsequent applications that support dissemination and implementation efforts through separate funding announcements.
Reproducibility and Transparency of Research

This component is included in the Research Plan Template. Describe the ability to replicate potentially important findings from PCORI-funded studies in other data sets and populations.

Protection of Human Subjects

This component is included in the Research Plan Template. Describe the protection of human subjects involved in your research. Federal regulations (45CFR46) require that applications and proposals involving human subjects must be evaluated with reference to the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained.

References Cited

This component is included in the Research Plan Template. Provide a list of references cited in the Research Plan. Each reference must include names of all authors (in the same sequence in which they appear in the publication), the article title, and journal or book title, volume number, page numbers, and year of publication. Include only bibliographic citations. Follow scholarly practices in providing citations for source materials relied on in preparing any section of the application. Citations that are publicly available in a free, online format may include URLs or PubMed ID (PMID) numbers along with the full reference. The references should be limited to relevant and current literature. It is important to be concise and to select only those literature references pertinent to the proposed research so that the 10-page limit is not exceeded. Websites should be reference in the standard URL format (i.e., http://www.pcori.org) with the date the link was last accessed.

Consortium Contractual Arrangements

This component is included in the Research Plan Template. Describe the proposed research projects that will be performed by subcontracted organizations. Explain the strengths that these partners bring to the overall project.

- Signed subcontract agreements are not required at the time of application submission to PCORI.
- The submission of an application to PCORI signifies that programmatic and administrative personnel from your organization and all proposed subcontract organizations who will be involved in this project are aware of your organization’s subcontract agreement policy and that all involved organizations are prepared to establish the necessary inter-organizational agreement(s) consistent with that policy.
- Information for subcontract personnel must be included in Key Personnel.
- Budget information for all subcontracted organizations must be included in the Budget Template, Budget Summary, and Budget Justification.

9 Available at http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html
Appendix (Optional)
This component is included in the Research Plan Template. As part of your research plan, you may provide an appendix of up to 10 pages to include additional materials that you think may be useful to describe (e.g., survey instruments, interview guides, etc.). Note, however, that reviewers are not required to include the appendix when they review and assess your application.

Professional Profile/Biosketch
This component is included in the People and Places Template. Complete a Professional Profile/Biosketch section for each person listed as a principal investigator, co-investigator, or other significant contributor, copying the tables provided in this section as needed. Please note that information from NIH biographical sketches can be incorporated. At a minimum, each profile must include the person’s name, title, and degrees, however, PCORI is especially interested to know each individual’s previous experience, past performance, and training in the field of PCOR and, secondly, that researchers, investigators, and other team members are appropriately trained and well-suited to carry out the research. If the principal investigator does not have PCOR experience, please outline appropriate collaborative arrangements with PCOR experts. Demonstrate the study team’s experience as it relates to the leadership approach, governance, and organizational structure appropriate for the project. Outline how the team’s complementary experience will serve to achieve the study aims as described. Note: PCORI recognizes that not all sections of the Professional Profile may apply to patient or stakeholder members of the research team.

Project/Performance Site(s) and Resources
This component is included in the People and Places Template. Starting with the primary research site first, list the organizational name, full physical address, city, county, state, zip code, and congressional district for each place where the work described in the Research Plan will be conducted.

Provide a description of the facilities, including their capacities, capabilities, relative proximity, and extent of availability to the project. Describe how the research environment contributes to the probability of success (e.g., institutional support, physical resources, and patient engagement). Discuss ways in which the proposed study will benefit from unique features of the research environment or community involvement or will employ useful collaborative arrangements. Finally, describe institutional and community investment in the success of the research, such as the availability of organized peer groups; logistical support, such as administrative management and oversight, and best practices training; financial support, such as protected time for research with salary support; and access to and support of patient groups.

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10 Available at http://pcori.org/assets/2013/09/PCORI-PFA-People-Places-Template.doc
Budget Template

Enter detailed budgets for Year One, Year Two, and Year Three in the worksheets provided in the Budget Template. Include all costs for your organization in the Applicant worksheets. If applicable, include all costs for each subcontracted organizations in the Subcontractor worksheets. Copy and complete a separate set of worksheets (Year One, Year Two, and Year Three) for each subcontracted organization. See Appendix 2: Allowable and Unallowable Costs to understand acceptable and unacceptable uses of PCORI contract funds.

Keep the following guidelines in mind as you complete each section of the worksheet.

A. Personnel Costs

- **Allowable Costs**: PCORI will pay compensation for personnel as long as the costs are consistent with and do not exceed what the applicant would normally pay under its own policy. Such compensation may include salaries and fringe benefits. See Appendix 2: Allowable and Unallowable Costs for more information.

- Salaries include wages earned by an employee, and eligible costs also include fringe benefits, including insurance and retirement plans. Note: Key personnel include those who, if they left, would significantly impact the project.

- **Level of Effort**: Personnel contributing to a PCORI-funded research project are expected to monitor their total percent effort across all funding (PCORI or others), and may not exceed 100%. Effort must be reported by the percentage of time over the course of the project year. All personnel from the applicant organization dedicating effort to the project should be listed on the personnel budget with their level of effort, even if they are not requesting salary support. Please list the base salary for such persons in the justification, using $0 for base salary within the detailed budget.

- **Salary Cap**: The PCORI base salary cap for personnel is $200,000 per individual, per year, exclusive of fringe benefits. An individual who earns less than $200,000 should use his/her actual base salary to calculate personnel costs. An individual with a base salary more than $200,000 must use $200,000 as the base salary rate in determining the amount of salary and time to charge to the project.

- **Fringe Benefits**: These costs are calculated based on the institution’s own policy. As referenced above, there is no cap on the fringe benefits rate.

- **Personnel Costs**: In addition to noting the base salary for each scientific/technical staff, you must note the base salary for each employee patient or stakeholder member of your research team, if these members are not accounted in Section B: Consultant Costs.

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11 Available at http://pcori.org/assets/2013/09/PCORI-PFA-Budget-Template.doc
B. Consultant Costs

- Consultant costs are those for individuals who have dedicated time to the project not as an employee of the applicant organization or under a subcontract agreement as a member of the contractor staff. Payments to non-employee patient and stakeholder representatives are included.
- Consultant costs must be expressed in an hourly rate.
- Consultant costs must be reasonable and justified within the budget justification.
- Provide total cost of consultant(s) as well as names, expected number of hours, and hourly rate.
- For all consultant costs, provide computations for how applicants arrived at the specific number.

C. Supply Costs

- Supplies are general-purpose consumable items that are used on a regular basis or other tangible items that do not meet the definition of equipment. Include the category of supplies needed and the cost for each.
- Tangible items with per-unit costs of $5,000 or more are considered equipment and cannot be accounted for under this category.
- Indicate general categories such as glassware, chemicals, animal costs, including an amount for each category.
- Include details for each cost that exceeds $1,000 in the space provided. You will be asked to provide further detail for each of these costs in the Budget Justification template.
- For all supply costs, provide computations for how you arrived at the specific number.

D. Travel Costs

- Travel may include any domestic and/or international travel by an employee or other personnel directly related to and necessary for the project and within the limits explained below.
- Travel costs should be itemized per trip and described as either scientific travel or programmatic travel, as outlined below:
  - **Scientific Travel**—including travel to present at conferences, symposiums, and so forth. Scientific travel is capped at $10,000 over the full project period, including costs for applicant organization and subcontractor personnel.
  - **Programmatic Travel**—including travel needed for the conduct of the project (i.e., focus groups, consultants, and others).
  - Airline costs cannot exceed those in excess of the customary standard commercial airfare (coach or equivalent) or the lowest commercial discount airfare.
  - PCORI reviews all travel costs for reasonableness.
  - PCORI will hold a research methods symposium where applicants will be asked to present their work. Applicants should budget to attend one, two-day meeting in Washington, DC. This should be budgeted for in the first year of the project’s duration.
- For each category of travel (scientific and programmatic), include number of trips and a brief description of the trips to include the number of people traveling, and dates or duration of the stay.
• In the justification, provide added detail to explain the basis for the costs listed and describe how the travel is directly related to the proposed research (and is necessary for achieving programmatic objectives) in the budget justification.

E. Other Expenses
• List the total for all other costs in the appropriate rows. Indicate general categories such as printing costs, publication costs, and service contracts, including an amount for each category.
• Use this section to include direct costs that cannot be accounted for in other budget categories. These costs may include travel costs or participation incentives for study subjects, publication costs, service contracts, or coverage of copayments/coinsurance.
• Include details for each cost that exceeds $1,000 in the space provided. You will be asked to provide further detail for each of these costs in the Budget Justification template.

F. Inpatient and Outpatient Costs
• List the total for inpatient costs and outpatient costs in the appropriate row.
• PCORI will cover project-related inpatient/outpatient costs that insurance does not cover.
• In the Budget Justification below, justify the costs associated with inpatient/outpatient care. Provide cost information for inpatient and outpatient care separately.

G. Equipment Costs
• List each item of equipment and its cost.
• Equipment costs include tangible items with a cost of $5,000 or more.
• Equipment costs must be approved by PCORI and must be reasonable and necessary for the project and not otherwise easily available or accessible at lower costs.
• In general, PCORI will allow equipment, when applicable, and only in the first year of the contract.

H. Subcontractor Costs
• This category includes all consortium, contractual, and fee-for-service costs. A Subcontractor Arrangement is required for an individual’s participation if the criteria listed below are met. If the criteria listed below are not met, a Consulting Agreement is more likely required. (See section B: Consultant Costs):
  o The time a person is devoting is on behalf of his/her employer and becomes part of his/her duties.
  o His/her effort on the project is calculated as part of his/her “professional time” for his/her employer organization.
  o The subcontractor will be using significant resources (e.g., office space, supplies, computer, personnel) at his/her own organization when working on the PCORI-funded project.
• The applicant organization is required to pay the subcontractor indirect costs associated with his/her participation.

• As stated above, complete a set of worksheets (Year One, Year Two, Year Three) for each subcontractor. Subcontracted organizations must adhere to all budget policies detailed in these guidelines, including allowable and unallowable costs.

• Enter the total amounts for the direct and indirect costs in the appropriate row.

• Direct Costs:
  o Subcontractor personnel should be listed as key personnel and included in that section of the application if they contribute to the scientific development or execution of the project in a substantive and measurable way.
  o Subcontractor direct costs entered in the applicant’s budget detail (Year One, Year Two, Year Three) must represent the total direct costs across all subcontracts.

• Indirect Costs:
  o Indirect costs for the project may be calculated according to the subcontractor’s own negotiated or audited indirect cost rate; however, the total indirect costs charged to project cannot exceed the PCORI indirect cost cap (see Section I: Indirect Costs). The Budget Template has a tab that includes a tool to calculate the subcontractor indirect cost cap for your application.
  o Subcontractor indirect costs are not included as part of the applicant organization’s direct cost base when determining whether prior approval is needed to submit an application.
  o Indirect costs entered in the applicant’s budget detail (Year One, Year Two, Year Three) represent the total indirect costs across all subcontracts.
  o The calculation used for subcontractor indirect costs is the same as that used for applicant organization indirect costs. See Section I: Indirect Costs.

I. Indirect Costs

• Enter the amount for indirect costs.

• Indirect costs for the project may be calculated according to the applicant’s own negotiated or audited indirect cost rate; however, the total indirect costs charged to project cannot exceed the PCORI indirect cost cap.

• The Budget Template contains a tool using the formula shown below to calculate the PCORI indirect costs cap. Note: foreign applicants will use the same calculation to determine their own indirect cost cap, but may only take up to 10 percent.
Budget Justification Template

Use the Budget Justification Template\(^\text{12}\) to provide a justification that supports the cost proposed in the budget for the applicant organization and for each subcontracted organization and the budget summary for all years.

- **Applicant Organization:** Provide the detail needed to understand both the basis for costs and the reason why the costs are necessary to the project for each budget category, providing adequate detail to understand any major cost variances. Additionally, the budget justification must specify any other sources of funding that are currently available or anticipated to support the proposed research project, including sources, amounts, and the time period for the other financial support. Finally, provide a summary justification to support each budget category for the full project period, providing adequate detail to understand any major cost variances.

- **Subcontracted Organization Justification(s):** Provide a detailed justification for each subcontract agreement by budget category. Specify any other sources of funding direct to the subcontractor in support of its portion of the project (see below). Also provide a summary justification to support each budget category for the full project period with adequate detail to understand any major cost variances.

- **Specifying Other Funding Sources:** Specify any other sources of funding that are currently available or anticipated to support your project, including sources, amounts, and the time period for the other financial support.

\(^{12}\text{Available at http://pcori.org/assets/2013/09/PCORI-PFA-Budget-Justification-Template.doc}\)
Letters of Support

Provide Letters of Support, including any letters necessary to demonstrate the support of subcontract participants and collaborators, such as principal investigators, investigators, stakeholder associations, and other significant contributors included in the contract application. You are also highly encouraged to include a letter of intent from the leadership of your organization indicating that the organization is supportive of implementing the research findings if they are germane and warranted for implementation. Letters of Support are not required for personnel (such as research assistants) who are not contributing in a substantive, measurable way to the scientific development or execution of the project.

Letters of Support must be addressed to the PI, combined into one PDF, and uploaded into PCORI Online.

6.0 Additional Requirements

Awardees are required to comply with the following requirements:

Required Education of Key Personnel on the Protection of Human Subject Participants

PCORI requires all applicants to adhere to NIH policy on education in the protection of human subject participants in the conduct of research. This applies to all personnel listed in the application as key personnel. The policy is available from the NIH website.  

PCORI Public Access Policy

PCORI contracts require all awardees to adhere strictly to PCORI’s publication policies. These policies will be shared with awardees.

Standards for Privacy of Individually Identifiable Health Information

The Department of Health and Human Services (HHS) issued a final modification to the Standards for Privacy of Individually Identifiable Health Information, the "Privacy Rule," on August 14, 2002. The Privacy Rule is a federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that governs the protection of individually identifiable health information and is administered and enforced by the HHS Office for Civil Rights (OCR).

Decisions about applicability and implementation of the Privacy Rule reside with the researcher and his/her institution. The OCR website provides information on the Privacy Rule, including a complete Regulation Text and a set of decision tools on "Am I a covered entity?" Information on the impact of the

13 Available at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html
14 Available at http://www.hhs.gov/ocr

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HIPAA Privacy Rule on NIH processes involving the review, funding, and progress monitoring of grants, cooperative agreements, and research contracts can be found at the [NIH website](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html).  

**Contract Terms and Conditions of Award**

The administrative and funding instrument used for FUNDED PROJECTS ARE contracts, not grants. As a funding organization, PCORI retains the right to administer programmatic oversight with awardees during the contract period. For additional information, see [PCORI Contract for Funded Research Projects](http://pcori.org/assets/2013/09/PCORI-PFA-Contract-for-Funded-Research-Projects.pdf).

**Award Funding Conditions**

PCORI reserves the right to discontinue funding for awardees who fail to meet the mutually agreed upon milestones at any time during the contract. Proposed milestones should be presented in the application, but final milestones will be negotiated in the post-award period prior to the beginning/activation of the funding period.

**Co-Funding**

PCORI partners with various other research organizations to leverage additional funds for some of its programs. If you currently have a funded project and would like to seek PCORI funding to add a new aim to the study that advances PCORI funding objectives, you may submit an application.

**Dissemination and Data Sharing**

PCORI is committed to the publication and dissemination of all information and materials developed using PCORI funding in accordance with its enacting legislation. All recipients of PCORI contracts must agree to these principles and must take steps in order to facilitate availability of data and samples.

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16 Available at http://pcori.org/assets/2013/09/PCORI-PFA-Contract-for-Funded-Research-Projects.pdf
7.0 How Does PCORI Review and Score Applications?

PCORI conducts rigorous merit review of the applications it receives. Note that applications may be eliminated from the review process for administrative or programmatic reasons. An application may be administratively triaged if it is incomplete or submitted past the stated due date and time, or it does not meet the administrative or formatting criteria outlined in this document, in the PCORI templates, in the PCORI Online System. An application may be programmatically triaged if it is not responsive to the guidelines as described in the PCORI PFA, if it describes research that is non-comparative, or if it otherwise does not meet PCORI programmatic requirements.

Review Process

In order to support high-quality patient-centered scientific research, PCORI’s merit review process is distinguished by the full participation of scientists, patients and their caregivers, and stakeholders. The review process includes an initial online review, in-person panel review, and post-panel review.

**Preliminary Review:** Four reviewers are assigned to evaluate each application—two scientists, one stakeholder, and one patient/caregiver reviewer. For applications that are purely analytic in nature, three scientific reviewers are assigned to evaluate each proposal. No patients or stakeholders will be assigned to these applications. Reviewers evaluate each application based on PCORI’s Review Criteria and submit an initial score for each criterion and provide an overall score. They also provide a detailed written critique that includes a list of strengths, weaknesses. The most meritorious applications are identified based on these scores and detailed critiques and. These applications advance to PFA-specific, in-person, merit review meetings.

**In-Person Panel Review:** A panel of reviewers, including the preliminary reviewers and additional scientists, patients, and other stakeholders, review each application. The panel size depends on a number of factors such as the total number of applications received in response to a particular funding announcement. The panel discusses each application’s strengths and weaknesses. Each panelist then assigns a final overall score to each application.

**Post-Panel Review:** After the in-person merit review meetings, the top-scored applications are assessed for impact and feasibility by members of PCORI’s Methodology Committee. Methodology Committee members who submitted applications as a Principal Investigator or Key Personnel are excluded from this process. Acting as peer-reviewers, they follow the same rules around confidentiality and disclosure of conflict of interest as other PCORI peer reviewers.

Following the impact and feasibility assessment, top-scored applications are reviewed by a Selection Committee that includes of members of PCORI’s staff and its’ Board of Governors. The Selection Committee identifies a slate of applications for possible funding based on merit review scores,
programmatic balance, and PCORI's strategic priorities. This slate is proposed to PCORI’s Board of Governors for their consideration and approval.

**Scoring**

During the Preliminary Review and the In-Person Panel Review, reviewers use the following nine-point scale to assign criterion scores, initial overall scores, and final overall scores. Letters of Intent are not scored.

<table>
<thead>
<tr>
<th>Range</th>
<th>Score</th>
<th>Descriptor</th>
<th>Characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>1</td>
<td>Exceptional</td>
<td>Exceptionally strong with essentially no weaknesses</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>Outstanding</td>
<td>Extremely strong with negligible weaknesses</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>Excellent</td>
<td>Very strong with only some minor weaknesses</td>
</tr>
<tr>
<td>Medium</td>
<td>4</td>
<td>Very Good</td>
<td>Strong but with numerous minor weaknesses</td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>Good</td>
<td>Strong but with at least one moderate weakness</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>Satisfactory</td>
<td>Some strengths but also some moderate weakness</td>
</tr>
<tr>
<td>Low</td>
<td>7</td>
<td>Fair</td>
<td>Some strengths but with at least one major weakness</td>
</tr>
<tr>
<td></td>
<td>8</td>
<td>Marginal</td>
<td>A few strengths and a few major weaknesses</td>
</tr>
<tr>
<td></td>
<td>9</td>
<td>Poor</td>
<td>Very few strengths and numerous major weaknesses</td>
</tr>
</tbody>
</table>
Appendix 1: Key Terms

Allowable Costs—A cost that is approved within the budget and is not otherwise unallowable under the PCORI Funded Research Policies. A direct cost is allocable to the project if the goods or services involved are chargeable or assignable to the project in accordance with relative benefits received or other equitable relationship. As a result, a cost is allocable to the funded project if (1) it is incurred solely to advance the work under the project, or (2) it benefits both the funded project and other work of the recipient organization, in proportions that can be approximated through use of reasonable methods.

Brief Abstract—A summary of the research plan written for a non-scientific audience. This abstract is made publicly available if the project is funded.

Biosketch—A profile of the experience and accomplishments of the key personnel in an application. Such a biosketch also satisfies the requirements of the PCORI Professional Profile.

Burden—A term that refers to the frequency of the condition, the expected mortality and morbidity, and/or the burden of suffering associated with symptoms, complications, or other consequences of the condition. Additionally, it may include the costs to the US population of healthcare services used, the individual patients’ out-of-pocket expenses, as well as intangible costs to the patient, such as time away from paid or unpaid occupations.

Clinical Practice Guidelines—Systematically developed statements or recommendations to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances. They present indications for performing a test, procedure, or intervention, or the proper management for specific clinical problems. Guidelines may be developed by government agencies, institutions, organizations such as professional societies or governing boards, or by convening expert panels.

Closeout—The process by which PCORI determines that all applicable administrative actions and all required work of the contract have been completed and officially closes the contract.

Comparative Effectiveness Research (CER)—The direct comparison of existing healthcare interventions to determine which interventions work best for which patients and which interventions pose the greatest benefits and harms. The core question of comparative effectiveness research is which treatment works best, for whom, and under what circumstances.

Conflict of Interest—As defined by PCORI’s authorizing legislation, a conflict of interest is any “association, including a financial or personal association, that has the potential to bias or have the appearance of biasing an individual’s decisions in matters related to the Institute or the conduct of activities” [Patient Protection and Affordable Care Act, Pub L No. 111-148, 124 Stat 727, §6301(a)(3)]. Conflicts of interest will be considered and managed throughout every step of the review and selection process, including, but not limited to, the technical and programmatic reviews, the selection and assignment of scientific and stakeholder reviewers, Board of Governors deliberations, and post-award negotiations and monitoring.

Consultant—An individual hired to provide professional advice or services for a fee.
**Contract**—The legally binding document that PCORI uses to make awards for research projects.

**Data Universal Numbering System (DUNS)**—A unique identifier assigned to a single business entity. You may apply for a DUNS number online. See [dandb.com/credit-resources/duns-number/how-to-get-and-maintain-a-duns-number](dandb.com/credit-resources/duns-number/how-to-get-and-maintain-a-duns-number).

**Employer Identification Number (EIN)**—The Federal Tax Identification Number used to identify a business entity. You may apply for an EIN in various ways, including online. See [irs.gov/businesses/small/article/0,,id=102767,00.html](irs.gov/businesses/small/article/0,,id=102767,00.html).

**Financial Official (FO)**—The individual designated by the recipient organization who is responsible for the proper accounting of contract funds and the submission of payment details. The FO is responsible for completing and certifying the required yearly expenditure reports.

**Fringe Benefits**—A form of pay for the performance of services. Fringe benefits commonly include health insurance, group term life coverage, and non-wage compensation.

**Indirect Costs**—Costs not directly accountable to the project. Indirect costs include taxes, administration, personnel, and security costs.

**Institutional Review Board (IRB)**—A group that follows federal regulations, state laws, and institutional policy to review, monitor, and approve research in order to protect the ethical rights and privacy of the subjects involved.

**Letter of Intent (LOI)**—A notification to PCORI that an organization intends to apply. Submission of an LOI is a prerequisite to submitting an application.

**Merit Review**—A review of applications by qualified reviewers who read, score, and provide feedback on the applications.

**Methodology Committee**—Per PCORI’s authorizing legislation, the 17-member group working to develop and advance scientific methods in patient-centered outcomes research. The Methodology Committee is a subtending committee that supports the PCORI Board of Governors.

**Patients**—Individuals who have or have had the condition under study; it may include patient surrogates or caregivers as well. It does not necessarily mean, but does not exclude, patient advocates or patient navigators.

**Patient-Centered Outcomes Research (PCOR)**—Research that helps people and their caregivers communicate and make informed healthcare decisions, while allowing their voices to be heard in assessing the value of healthcare options. This research answers patient-centered questions. A full definition can be found at: [pcori.org/what-we-do/pcor](pcori.org/what-we-do/pcor).
PCORI Funding Center—A location on PCORI’s website where applicants can access all templates, guidelines, information, and training needed to prepare and submit an application. See pcori.org/apply.

PCORI Online System—PCORI’s online application and management system, designed to facilitate the applicant’s submission of materials, and the activation of a contract through completion and closeout. See contracts1.pcori.org

Principal Investigator (PI)—Lead scientist(s) for a research project. The primary Principal Investigator on a contract or application for funding who serves as PCORI’s primary point of contact for that contract or application.

Professional Profile—A profile of the experience and accomplishments of a person who will play a significant role on a PCORI-funded research project. See also biosketch.

Programmatic Review—A review of the scientific portion(s) of the application to ensure that it meets PCORI’s programmatic requirements.

Public Abstract—A summary of the research plan that is written for, and will be accessible to, a general, lay audience.

Randomized Controlled Trial (RCT)—An experiment in which participants are randomly allocated to receive one of two (or more) diagnostic, preventive, therapeutic, or palliative interventions and are then followed to determine the effects of the intervention.

Reasonable Costs—A cost may be considered reasonable if the nature of the goods or services acquired or applied is appropriate and justifiable. The amount involved reflects the action that a prudent person would have taken under the circumstances prevailing at the time the decision to incur the cost was made.

Renewed Support—Approval of an additional funding period for the same project within the approved project period. The original agreement will remain in place and additional funds obligated near the end of each funding period. Any funds remaining on the contract prior to the new obligation will remain available for the recipient’s use.

Research Team—A group of people organized to function cooperatively to design and conduct research. For PCORI, teams should include patients and other stakeholders as key contributors to the research process.

Scientific Review Officer (SRO)—A scientist who presides over a scientific merit review panel and is responsible for coordinating and reporting the discussion of each application assigned to it. The SRO serves as an intermediary between the applicant and reviewers, and prepares summary statements for all applications reviewed.
**Senior/Key Personnel**—Individuals who contribute to the scientific development or execution of the project in a substantive and measurable way. The contribution is independent of financial compensation.

**Stakeholders**—Includes clinicians (e.g., physicians, nurses, pharmacists, counselors, and other providers of care and support services); patient-advocacy groups; community groups; researchers; health-related associations; policy makers; and organizational providers, purchasers, payers, and industries for whom the results of the research will be relevant.

**Technical Abstract**—A summary of the research plan that is written for scientists and researchers.
Appendix 2: Allowable and Unallowable Costs

Acceptable uses of PCORI contract funds are those that directly support the proposed research project, including collection and analysis of data and obtaining relevant data sets. Overall, costs include salaries and fringe benefits for study investigators and other project staff (including patient and stakeholder partners), consultant fees, travel for investigator meetings (both in person and via teleconference), travel that is clearly project-related, supplies, equipment in the first year, subcontract agreements, and other direct research expenses, and indirect costs. Unallowable costs should not be included either as direct costs or through an indirect cost pool. The examples listed below are not considered allowable under PCORI contracts. These examples are not all-inclusive. PCORI reserves the right to review each cost associated with a contract.

<table>
<thead>
<tr>
<th>Allowable Costs</th>
<th>Unallowable Costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Personnel Salaries &amp; Benefits</td>
<td>Advertising</td>
</tr>
<tr>
<td>Consultant Fees</td>
<td>Donations</td>
</tr>
<tr>
<td>Equipment</td>
<td>Excessive Airfare</td>
</tr>
<tr>
<td>Supplies</td>
<td>Alcoholic Beverages</td>
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<tr>
<td>Subcontractor Direct &amp; Indirect</td>
<td>Personal Expenses</td>
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<tr>
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<td>Student Housing</td>
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<td>Applicant Indirect Costs</td>
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<td>Lobbying</td>
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