PCORI Grant Application Instructions

I. Foreword

The PCORI Grant Application Instructions contain information for preparing an application to the Patient-Centered Outcomes Research Institute (PCORI) in response to a published PCORI Funding Announcement (PFA).

The PCORI Grant Application Instructions are organized to follow the PCORI Grant Application from start to finish and guide the applicant through the required contents.

Announcements about funding opportunities are made through a PCORI Funding Announcement (PFA), a formal document that solicits grant or cooperative agreement applications in a well-defined area of interest to accomplish specific program objectives. PFAs provide the information specific to a funding program. Both the Grant Application Instructions and the PFA are needed to respond responsively and competitively.

PCORI Funding Announcements will be made available on the PCORI website (www.pcori.org) and will be publicized through other communication vehicles, such as newsletters, email distribution lists, press releases, or other public announcements. To subscribe to the PCORI Newsletter visit www.pcori.org.

All applications to PCORI for funding must be submitted in response to a specific PFA that has been publically announced or published by PCORI. Unsolicited applications that are not in response to a specific PCORI Funding Announcement will not be accepted.

II. General Instructions

Format Specifications

Follow font and format specifications to avoid processing delays or rejection of the application.

Font and Graphics

- Use an Arial typeface, a black font color, and a font size of 11 points or larger. Special characters may be used but must be 11 points.
- Type should be formatted to be easy to read in black type, a type density of no more than 15 characters per inch, and no more than six lines per inch. Do not use color or shading within the text.
- A smaller type size is acceptable for figures, graphs, diagrams, charts, legends, and footnotes, but must be in black ink and easily legible.

Page Formatting

- Use letter size (8 ½” x 11”) sheets of paper.
- Use at least one inch margins (top, bottom, left, and right) for all pages, including continuation pages. No information should appear in the margins, including the PI’s name and page numbers.
- Use only a standard, single-column format for the text.
- The application must be single-sided and single-spaced.
- Consecutively number all pages throughout the application, including continuation pages. Do not use suffixes (e.g., 5a, 5b).
- Do not include additional pages between the Form A: Face Page and Form B: Table of Contents (page 2).
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- All photographs and other materials must be embedded within the document and cannot be affixed using glue or tape.

**Packaging**
- Submit the following materials in one package:
  - Optional cover letter (original only)
  - Original application
  - Required number of copies
- The original application must have the required signature on the Face Page.
- Do not staple or otherwise bind the original application. Rubber bands or clips are acceptable.

**Order of the Submitted Application and Page Limits**
Applications must be compiled in the order shown below and within the associated page limits for each section. Each page must be numbered in consecutive order with no page number extensions such as 5a, 5b.

<table>
<thead>
<tr>
<th>SECTION OF APPLICATION</th>
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<td>Optional Cover Letter (Placed on top of the original application.)</td>
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<td>Form A: Face Page</td>
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<td>Form F: Consolidated Budget Summary for Entire Proposed Project Period</td>
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<td>Form G: Direct Costs Budget Summary(ies) (for Applicant Organization)</td>
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<td>Forms G-1—G-7 Direct Costs Budget Details (for Applicant Organization)</td>
<td>As needed</td>
</tr>
<tr>
<td>Form G: Direct Costs Budget Summary(ies) (for Consortium/Contracts)</td>
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<td>Forms G-1—G-7 Direct Costs Budget Details (for Consortium/Contracts)</td>
<td>As needed</td>
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<tr>
<td>Form H: Resources</td>
<td>As needed</td>
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<tr>
<td>Form I: Biographical Sketches</td>
<td>4 pages each</td>
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<td>Form J: Checklist</td>
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<td>PCORI Pilot Projects Addendum Form: Areas of Interest</td>
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<td>Research Plan: Specific Aims</td>
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<td>Research Plan: Research Strategy</td>
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### Optional Cover Letter
Applicants may include a cover letter with the application. This letter is only for PCORI use and will not be shared with peer reviewers. Place the letter on top of the original application submitted; do not copy it. The letter, if submitted, should include:

- Application title
- PCORI Funding Announcement (PFA) title and date
- List of individuals (e.g., competitors or those with a conflict of interest) who should not review the application and the reason why.

### III. Specific Instructions
Below are the specific instructions for each form. Use the forms provided, attaching continuation pages as needed within page restrictions.

#### Form A: Face Page

**General**
- The Face Page must be printed on a single page.
- The information provided on the Face Page of the application and the fiscal information must be verified by the official signing for the applicant organization.

**Item 1. Title of Project**
Choose a descriptive title that is appropriate to the specific PFA. Do not exceed 81 characters, including the spaces between words and punctuation.

**Item 2. Responding to the following PCORI Funding Announcement**
Indicate the title and number of the specific PCORI Funding Announcement to which the application is in response, unless already provided on the Face Page.

**Item 3. Principal Investigator(s) (PI)**

**Item 3a. Name of Principal Investigator (PI)**
Name the single contact person responsible to the applicant organization for the scientific or technical direction of the project. PCORI staff conducts official business only with the named PI and institutional officials.
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**Item 3b. Degree(s)**
Indicate up to three academic and professional degrees or other credentials, such as licenses (e.g., R.N.), for the PI.

**Item 3c. Position Title**
Provide the academic or professional title of the PI. If more than one title, indicate the one most relevant to the proposed project (e.g., Professor of Biochemistry, Chief of Surgical Service, or Group Leader).

**Item 3d. Mailing Address and E-mail Address**
Under “mailing address” provide complete information (including room number, building, and street address) necessary for postal delivery. All written communications with the PI will use this address. Under e-mail address, provide the appropriate e-mail address for the PI.

**Item 3e. Organization & Department, Service, or Equivalent**
Indicate the name of the organization the PI is affiliated with, along with other clarifying information such as Department of Medicine, or Social Sciences Institute.

**Item 3f. Major Subdivision**
Indicate school, college, or other major subdivision, such as medical, dental, graduate, nursing, or public health. If there is no such subdivision, enter “None.”

**Item 3g. Telephone and Fax Numbers**
Provide a daytime telephone number and, if available, a fax number.

**Item 3h. ERA Common Users Name**
The Commons User Name is the ID assigned to and used by the individual to access the eRA Commons. PIs who have served on grant projects funded by NIH are required to be registered in the eRA Commons. If the PI has a Commons User Name, enter it here. Otherwise, enter “none”.

**Item 4. Human Subjects Research**
PCORI has adopted the human subjects research requirements of the U.S. Department of Health and Human Services found within 45 CFR Part 46. As a result, the requirements of this item mirror those of HHS.

**No Human Subjects Involved**
Check “No” if activities involving human subjects are not planned at any time during the proposed project period. The remaining parts of Item 4 are then not applicable.

**Human Subjects Involved**
Check “Yes” if activities involving human subjects are planned at any time during the proposed project period. Check “Yes” even if the research is exempt from HHS regulatory requirements for the protection of human subjects. For more information about exemptions visit the following link:
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.101

If you plan to conduct research involving human subjects, you must include item 4 of the Research Plan (Protection of Human Subjects). Note: Certification of IRB review and approval must be provided and accepted by PCORI before the award is made.
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**Item 4a. Exemptions from Department of Health and Human Services (DHHS) Human Subjects Regulations**
Check “Yes” if the proposed activities are exempt from the regulations within 45 CFR Part 46 found at http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.101. Insert the exemption number(s) corresponding to one or more of the six exemption categories. For more information about the exemptions see http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.101

Check “No” if any of the planned activities involving human subjects are not exempt, and complete Item 4b.

**Item 4b. Federal-Wide Assurance Number (Human Subjects)**
If the applicant organization has a current approved Federal-Wide Assurance (FWA) on file with the Office of Human Research Protections (OHRP), enter the number in the space provided. (See OHRP website at http://www.hhs.gov/ohrp/)

Enter “None” in Item 4b if the applicant organization does not have an approved FWA on file with OHRP. In this case, the signature on the Face Page is a declaration that the applicant organization will comply with 45 CFR Part 46 and proceed to obtain a FWA. (See OHRP website at http://www.hhs.gov/ohrp/)

**Item 4c. Reserved**
Leave blank.

**Item 4d. Reserved**
Leave blank.

**Item 5. Reserved.**
Leave both 5 and 5a blank.

**Item 6. Dates of Proposed Period of Support**
Enter the beginning and ending dates of the proposed period of support. Enter the full period of support requested, even if greater than the initial budget period. See the specific PFA for limitations.

**Item 7. Costs for Initial Budget Period**

**Item 7a. Direct Costs**
From Form F: Budget Summary for the Entire Proposed Project Period, enter the number found in Column 2: Initial Budget Period from the line marked “Subtotal Direct Costs.”

**Item 7b. Total Costs**
From Form F: Budget Summary for the Entire Proposed Project Period, enter the number found in Column 2: Initial Budget Period from the line marked “Total Costs.”

**Item 8. Costs Requested for Proposed Period of Support**

**Item 8a. Direct Costs**
From Form F: Budget Summary from the Entire Proposed Project Period, enter the amount found in the line marked “Total Direct Costs for the Entire Proposed Project Period.”

**Item 8b. Total Costs**
From Form F: Budget Summary from the Entire Proposed Project Period, enter the amount found in the line marked “Total Costs for the Entire Proposed Project Period.”
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**Item 9. Applicant Organization**
Enter the name and mailing address of the single organization that will be legally and financially responsible for the conduct of activities supported by the award.

**Item 10. Type of Organization**
Check the appropriate box. Below are the definitions for each option. If the applicant organization does not meet any of the following definitions, but is an eligible applicant in the relevant PCORI Funding Announcement, then leave this section blank, which will be considered as “other”.

**Public**
- **Federal**: A cabinet-level department or independent agency of the Executive Branch of the Federal Government or any component part of such a department or agency that may be assigned the responsibility for carrying out a grant-supported program.
- **State**: Any agency or instrumentality of a state government of any of the United States or its territories.
- **Local**: Any agency or instrumentality of a political subdivision of government below the State level.

**Private**
- **Nonprofit**: An institution, corporation, or other legal entity no part of whose net earnings may lawfully inure to the benefit of any private shareholder or individual.

**For Profit**
Choose the option that most closely fits the applicant organization.

- **General**: An institution, corporation, or other legal entity, which is organized for the profit or benefit of its shareholders or other owners. Select “General” if the applicant organization does not meet the definitions for small business, woman-owned business, or socially and economically disadvantaged business as outlined below.
- **Small Business**: A “for profit” organization is considered to be a small business if it is independently owned and operated, if it is not dominant in the field in which research is proposed, and if it employs no more than 500 persons.
- **Women-Owned**: A small business concern that is at least 51% owned by a woman or women who also control and operate it. “Control” in this context means exercising the power to make policy decisions. “Operate” in this context means being actively involved in the day-to-day management.
- **Socially and Economically Disadvantaged**: A socially and economically disadvantaged small business concern is one that is at least 51% owned by (a) an Indian tribe or a native Hawaiian organization, or (b) one or more socially and economically disadvantaged individuals; and whose management and daily business operations are controlled by one or more socially and economically disadvantaged individuals.

**Item 11. Entity Identification Number and Congressional District**

**Entity Identification number**
If the applicant organization has a nine-digit Internal Revenue Service employer identification number (EIN) enter it here or the words “Applied for” to indicate that the organization does not have an EIN but has applied to the local office of the IRS for one.
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**Congressional District**
Enter the state and district number of the Congressional District in which the applicant organization is located. To locate the appropriate district see the US Congress website at http://www.congress.org/congressorg/dbq/officials/?lvl=L.

**Item 12. Administrative Official to be Notified if Award is Made**
Name the applicant organization administrative official to be notified if an award is made. Provide a complete address for postal delivery and the telephone, fax, and e-mail address for the administrative official.

**Item 13. Official Signing for Applicant Organization**
Name an individual authorized to act for the applicant organization and to assume the legal and oversight obligations for a grant application or a grant award. Provide a complete address for postal delivery and the telephone, fax, and e-mail address for the signing official.

**Item 14. Applicant Organization Certification and Acceptance**
An original signature and date, in blue ink, is required. Enter the date signed. In signing the application Face Page, the Authorized Official certifies that the applicant organization will comply with all applicable policies, assurances and/or certifications referenced in the application and PFA.

**Form B: Table of Contents**
Provide the page number for each category listed on the Table of Contents.

Place page numbers at the bottom of each page, and consecutively number pages throughout the application, including continuation pages generated by the applicant, where allowed. Do not include unnumbered pages, and do not use suffixes, such as 5a, 5b.

**Form C: Description**
In completing this form, do not exceed the space provided and use text only (no figures or other information not in standard text). Do not include proprietary or confidential information, or trade secrets in the description section. If the proposed project is funded, the project description will be entered into a PCORI database and will become public information.

**Project Summary**
The first component of the description is a Project Summary. It is meant to serve as a succinct and accurate description of the proposed work when separated from the application. State the application's broad, long-term objectives and specific aims, making reference to the relatedness of the project to the program requirements as defined in the specific PFA. Describe concisely the research design and methods for achieving the stated goals. This section should be informative to other persons working in the same or related fields and, insofar as possible, understandable to a lay reader. Avoid describing past accomplishments and the use of the first person.

**Relevance**
The second component of the description is Relevance. Using no more than a paragraph, describe the relevance of this research to the mission and goals of PCORI. Be succinct and use plain language that can be understood by a general, lay audience.
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Form D: Project/Performance Site(s)
Indicate where the work described in the Research Plan will be conducted. Duplicate the form, as needed, to provide the full list of sites. Provide an explanation on Form H: Resources and state whether a consortium/contractual arrangement is involved with one or more collaborating organizations for the conduct of a portion of the work described in the Research Plan.

Form E: Senior or Key Personnel and Other Significant Contributors

Key Personnel
Start with the Principal Investigator(s). List the PI’s last name first. When multiple PIs are proposed, list the contact PI first, then all additional PIs in alphabetical order. Then list all other senior and key personnel in alphabetical order, last name first. For each individual provide the name, organization name (institutional affiliation), and role on the project. Under role on the project, succinctly indicate how the individual will function on the proposed project. Use additional consecutively numbered pages as necessary.

In addition to the PI, senior and key personnel are defined as individuals who contribute to the scientific development or execution of the project in a substantive, measurable way, whether or not salaries are requested. Key personnel must devote measurable effort to the project.

Other Significant Contributors
List all significant contributors not already listed in key personnel in alphabetical order, last name first. For each individual, provide the name, organization name (institutional affiliation), and role on the project. Under role on the project, succinctly indicate how the individual will function on the proposed project. Use additional consecutively numbered pages as necessary.

This category identifies individuals who have committed to contribute to the scientific development or execution of the project, but have not committed to any specified measurable effort to the project. Consultants should be included if they meet this definition.

Form F: Budget Summary for the Entire Proposed Project Period
From the detailed budget forms, enter summary information that shows each year’s proposed budget by budget category. Include only direct costs in the Section I, including for consortia and contracts. Address indirect costs in the Section II for both the applicant organization and a total for all consortia and contracts. Enter Subtotal and Total where indicated. Provide information for each year of the proposed project period within the limits described in the specific PFA.

Form G: Direct Costs Budget Detail
Applications must include a separate Form G, including detail pages (G1–G7), for the applicant organization and for each consortium member and contractor for each proposed budget year. Compile this required budget information using the following order:

1. Information for the applicant organization’s costs for the initial budget period.
2. Information for the applicant organization’s costs for each successive budget period, in order.
3. Information for each consortium member or contractor for the initial budget period.
4. Information for each consortium member or contractor for each successive budget period, in order.
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If the proposed budget does not include a request for funding in a particular budget category, include the page with zeros. All budget items must clearly relate to the project and be fully justified.

List only the direct costs, in US dollars. Do not include any items that are treated by the applicant organization or its consortia and contractors as indirect costs. Composite budget information for the entire project and all years, and information on indirect costs, are included on Form F.

**Form G: Direct Costs Budget Summary**

**Budget For.** Enter either “Applicant Organization” or the name of the consortium member/contractor that the form relates to.

**Budget Year.** Enter either “Initial” for the first year of the proposed project period or “Second”, “Third”, etc.

**Start Date and End Date.** Enter the date the proposed single-year budget period begins and ends.

**Budget Categories.** For the remainder of the form, enter the total requested amount for the year for each category, including only the applicant organization’s costs in lines 1 through 6 and the total of all consortia/contract costs in line 7.

**Total Direct Costs.** Enter the total for all lines in line 8.

**Form G-1: Direct Personnel Costs Budget Detail**

**Name.** Starting with the PI(s), list the names of all applicant organization employees who are involved on the project during the proposed budget period, regardless of whether a salary is requested. Include all collaborating investigators, individuals in training, and support staff.

**Role on Project.** Identify the role of each individual listed on the project. Describe their specific functions in the Justification section. This includes any “to-be-appointed” positions.

**Percentage of Time Devoted to Project.** Enter the percentage of time devoted to the project for each person.

**Institutional Base Salary.** Enter the base salary for each person listed in US dollars.

**Salary Requested.** Indicate only the dollar amount of salary being requested for the proposed budget period for each individual listed.

**Fringe Benefits.** Enter the dollar amount of fringe benefits associated with the salaries requested. Fringe benefits may be requested in accordance with the applicant organization’s guidelines for each position, provided the costs are treated consistently by the applicant organization as a direct cost to all funders. Provide the basis for costs in the Justification Section.

**Cost.** Calculate the totals for each position and enter the subtotals at the end of each row, where indicated.

**Subtotals for Personnel.** Total each column to provide a subtotal for salaries, for fringe benefits, and for total costs.

**Budget Justification.** Enter a justification for the personnel costs as indicated within the instructions above for this section.
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**Form G-2: Direct Consultant Costs Budget Detail**

Whether or not costs are involved, provide information for all consultants, other than those involved in consortium/contractual arrangements. Include consultants who are confirmed to serve on external monitoring or advisory committees.

**Consultant Name.** Enter the name of the consultant.

**Organizational Affiliation.** Enter the organizational affiliation for each consultant.

**Expected Hours.** Enter the number of hours of anticipated consultation for the consultant.

**Fees.** Enter the expected dollar amount of total compensation.

**Travel.** Enter the expected dollar amount of travel costs for each consultant, providing the basis for costs and reasons for travel in the justification below.

**Other.** Enter the expected dollar amount of other costs for each consultant, providing a description of those costs, reasons, and basis in the justification below.

**Cost.** Enter the sum of all costs for each row in the last column.

**Subtotal for Consultant Costs.** Enter the total for all lines in the cost column.

**Budget Justification.** Enter a justification for the consultant costs as indicated within the instructions above for this section.

**Form G-3: Direct Equipment Costs Budget Detail**

List each item of equipment with dollar amount requested separately. Note: Equipment is an article of tangible, nonexpendable, property having a useful life of more than one year and an acquisition cost of $5,000 or more, or the capitalization threshold established by the organization, whichever is less.

**Item of Equipment.** Enter the name or short description of each item of equipment to be purchased. Justify each purchase in the justification below.

**Cost.** Enter the total dollar amount requested for each item of equipment.

**Subtotal for Equipment Costs.** Enter the total for all rows in the last column.

**Budget Justification.** Enter a justification for the equipment costs as indicated within the instructions above for this section.

**Form G-4: Direct Supplies Costs Budget Detail**

Provide dollar amounts requested for supplies within separate categories. Supplies are non-capital items needed to carry out the project such as office supplies, items needed for research, and other items that are consumable and without value after their use or are items that would otherwise be considered equipment but have an acquisition cost of less than $5,000 or are not capitalized by the applicant organization.

**Supply Category.** Enter the name or short description of the supply category. Justify each category in the justification below, providing enough information to understand the type of supplies within the category or by itemizing them.
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**Cost.** Enter the total dollar amount requested for each category of supplies.

**Subtotal for Supply Costs.** Enter the total for all rows in the cost column.

**Budget Justification.** Enter a justification for the supply costs as indicated within the instructions above for this section.

**Form G-5: Direct Travel Costs Budget Detail**
Provide dollar amounts requested for travel by individual trip.

**Purpose.** Enter the reason for the travel, justifying its importance to the project under justification below.

**Destination.** Enter the destination for the trip. If the destination is not yet known, enter “unknown” and explain in the justification below.

**Number of People.** Enter the number of people traveling for each trip for whom funding is being requested. Explain the reason for multiple travelers in the justification below.

**Cost.** Enter the total dollar amount requested for each trip.

**Subtotal for Travel Costs.** Enter the total for all rows in the cost column.

**Budget Justification.** Enter a justification for the travel costs as indicated within the instructions above for this section. Include information on the basis for costs, such as the applicant organization’s policy for maximum allowable costs for hotel and per diem.

**Form G-6: Other Direct Costs Budget Detail**
Itemize all other direct costs that cannot be accounted for in other budget categories. These might include patient/participant travel, participation incentives, publication costs, computer charges, rentals and leases, equipment maintenance, service contracts, etc.

**Itemized Expenses.** Enter the name or short description of each item. Fully describe and justify each expense, including its importance to the project.

**Cost.** Enter the corresponding cost for each item under “Cost,” providing the basis for the cost under justification below.

**Subtotal for Other Direct Costs.** Enter the total for all rows in the cost column.

**Budget Justification.** Enter a justification for each itemized expense as indicated within the instructions above for this section.

**Form G-7 Direct Consortium/Contractual Costs Budget Detail**
Enter information for each consortium member or contractor, providing only their direct costs here.

**Consortium Member Organization or Contractor.** Enter the name of the consortium member or contractor organization. If the name of a contractor is not yet known, enter a brief description of the contract and explain within the justification below.

**Cost.** Enter the total dollar amount requested for consortium or contractor. Include direct costs only.
Subtotal for Consortium/Contractual Costs. Enter the total for all rows in the cost column.

Budget Justification. Enter a justification for costs as indicated within the instructions above for this section. Include information on the basis for costs and need for the partnership or contract.

Form H: Resources
This information is used to assess the capability of the organizational resources available to perform the proposed project. If there are multiple performance sites, describe the resources available at each site.

- Provide information on the facilities to be used in the proposed research in the order identified on Form D: Project/Performance Sites. If appropriate, indicate their capacities, pertinent capabilities, relative proximity and extent of availability to the project. Describe only those resources that are directly applicable to the proposed 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.

- 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.

Form I: Biographical Sketches
This section must contain the biographical sketches of all Senior and Key Personnel and Other Significant Contributors, following the order as listed on Form E: Senior and Key Personnel.

Use Form I to complete the first portion of the sketch and to begin the text. Attach additional pages for the narrative as needed, up to a total of 4 pages for each sketch, including the table at the top of the first page. If preferred, the applicant may recreate this form provided it includes all of the same information in the same order as listed.

Note: To see an example of a completed sketch, go to: http://grants.nih.gov/grants/funding/phs398/phs398.html#biosample

Name. Enter the name of the person who is denoted as Senior or Key Personnel or as an Other Significant Contributor.

Position Title. Enter the title of the person. If the person holds multiple titles, enter the one most relevant to the project.

Institution and Location. Enter the name and location of the institution for each degree the person holds or where they have studied.

Degree. Enter the degree the person holds beginning with baccalaureate or other initial professional education, such as nursing (R.N.). Include postdoctoral training and residency training if applicable and then list other degrees in the order they were conferred. If no degree was conferred, enter NONE or PENDING if not yet complete.

Date. Enter the month and year each degree was conferred. If no degree has been conferred, leave blank or enter the anticipated date of completion.
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Field of Study. Enter the field of study for each institution listed.

Sketch. Complete the biographical sketch for each person who is considered Key Personnel and Other Significant Contributors in the free-form narrative area, using additional pages as needed, up to a total of four pages per person. Use the following format:

- **Personal Statement.** Briefly describe why your experience and qualifications make you particularly well-suited for your role in the project that is the subject of the PCORI grant application.
- **Positions and Honors.** List in chronological order previous positions, concluding with the present position. List any honors. Include present membership on any public advisory committee.
- **Research Support.** List both selected ongoing and completed research projects for the past three years. Begin with the projects that are most relevant to the research proposed in the PCORI application. Briefly indicate the overall goals of the projects and responsibilities of the key person identified on the Biographical Sketch. As part of the biosketch section of the application, “Research Support” highlights the individual and collective accomplishments of the proposed research team. Reviewers will use this information to assess each individual's qualifications for a specific role in the proposed project, as well as to evaluate the overall qualifications of the research team.

Form J: Checklist

1. **Type of Application.** Select the appropriate boxes and enter the information requested for each selected box to the right.

2. **Patient-Focused Areas.** Select all patient-centered questions applicable to proposed research.

3. **Target Populations.** Select all populations that the proposed research will specifically target.

4. **Certification.** If the applicant organization agrees to comply with PCORI's rules and policies as described, indicate so by checking the box.

PFA-Specific Addenda

Check the specific PFA to determine if additional forms are required and complete them according to the instructions found within the PFA or on the specific form.

Content of Research Plan

There is no form provided for this section. Applicants will create this section in a narrative format. Keep content within the page limit as listed in the General Instructions section or as otherwise indicated within the specific PFA.

The Research Plan consists of the following 7 items. Begin each section of the Research Plan with a section header (e.g., Specific Aims, Research Strategy, etc.) and follow the same order as shown below.

1. Specific Aims
2. Research Strategy (Significance, Innovation and Approach)
3. References Cited
4. Protection of Human Subjects
5. Consortium/Contractual Arrangements
6. Letters of Support
7. Resource Sharing Plan(s)
Section 1. Specific Aims
State concisely the goals of the proposed research and summarize the expected outcome(s), including the impact that the results of the proposed research will have on PCORI areas of interest.

List succinctly the specific objectives of the research proposed as relevant to the objectives stated in the specific PFA (e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop new technology).

Specific Aims are limited to one page.

Section 2. Research Strategy
Organize the Research Strategy in the order specified below using the instructions provided. Start each section with the appropriate section heading—Significance, Innovation, Approach. Cite published experimental details in the Research Strategy section and provide the full reference in the References Cited section.

Follow the page limits for the Research Strategy as specified in the PFA.

(a) Significance.
- Explain the importance of the problem or critical barrier to patient-centered outcomes research.
- Explain how the proposed project will address one or more of the four patient-centered questions from the definition of PCOR, improve clinical practice and patient experience of care in one or more broad fields, or engage patients in their health care.
- Describe how the patient’s experience of health care will be improved by the concepts, methods, technologies, treatments, services, or preventative interventions if the proposed aims are achieved.
- Explain which of the PCORI areas of interest are being addressed by the proposal.

(b) Patient/Stakeholder Engagement.
- Describe how the research will make a unique contribution to learning about engagement of patients and stakeholders in PCOR research efforts.
- Demonstrate how the project will include authentic, feasible, sustainable, novel partnerships with patients, families and caregivers, providers, and other appropriate stakeholders.

(c) Innovation.
- Explain how the proposed project challenges and seeks to shift current research, intervention, clinical practice or patient engagement paradigms.
- Describe any new methods, application of proven methods in novel ways, or refinement, improvement, or new application of theoretical concepts, approaches, or methodologies, instrumentation or intervention(s) to be developed or used, and any advantage over existing methodologies, instrumentation or intervention(s).
- Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation, or interventions.

(d) Approach.
- Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Include how the data will be collected, analyzed, and interpreted as well as any resource sharing plans as appropriate.
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- Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims.
- If the project is in the early stages of development, describe any strategy to establish feasibility, and address the management of any high-risk aspects of the proposed work.
- Point out any procedures, situations, or materials that may be hazardous to personnel and precautions to be exercised.
- Describe any plans for dissemination of results to key PCORI stakeholders.

Section 3. References Cited
Provide a bibliography of any 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 and journal title, book title, volume number, page numbers, and year of publication. Include only bibliographic citations. Follow scholarly practices in providing citations for source materials relied upon 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. While there is not a page limitation, it is important to be concise and to select only those literature references pertinent to the proposed research.

Section 4. Protection of Human Subjects
If the proposed research will involve human subjects, refer to the Supplemental Instructions for Preparing the Protection of Human Subjects Section of the Research Plan in Part II of the Instructions for the PHS 398 Form as found at this link on the NIH website: www.grants.nih.gov/grants/funding/phs398/phs398.doc

Section 5. Consortium/Contractual Arrangements
Explain the programmatic, fiscal, and administrative arrangements to be made between the applicant organization and the consortium/contractor organization(s). If consortium/contractual activities represent a significant portion of the overall project, explain why the applicant organization, rather than the ultimate performer of the activities, should be the grantee.

The signature of the Authorized Organization Representative on the Face Page signifies that the applicant and all proposed consortium participants understand and agree to the following statement: The appropriate programmatic and administrative personnel of each organization involved in this grant application are aware of the applicant organization’s consortium agreement policy and are prepared to establish the necessary inter-organizational agreement(s) consistent with that policy.

Section 6. Letters of Support
Provide all appropriate letters of support, including any letters necessary to demonstrate the support of consortium participants and collaborators such as Key Personnel and Other Significant Contributors included in the grant application. Letters are not required for personnel (such as research assistants) not contributing in a substantive, measurable way to the scientific development or execution of the project. For consultants, letters should include rate/charge for consulting services. Consultant biographical sketches should be included in the Biographical Sketch section.