**PCORI PROPOSAL TEMPLATE:**

**COVID-19-RELATED ENHANCEMENT FOR EXISTING RESEARCH**

*Provide the information requested below. Do not exceed 2 pages. Email the completed template as a single PDF along with pdfs of the Budget Summary and Budget Justification.*

*Please provide a detailed description of the proposed COVID-19-related enhancement to your current PCORI award including the population, intervention, comparators, outcomes, timing, and setting. This must include the scientific rationale for the enhancement, a timeline of the proposed enhancement, and major deliverables necessary to achieve the proposed enhancement’s aims. Explain how the proposed enhancement will contribute timely information to address the coronavirus pandemic and public health response. The description should also include what existing study personnel, infrastructure, processes, etc., will be leveraged to facilitate efficient completion of the proposed enhancement. Integration, complementarity, and/or lack of interference with the original study should also be described. Indicate whether your current award is halted, and if so, which aspect is halted (recruitment, intervention delivery, etc.), and whether this affects your ability to enact the proposed enhancement. You may delete this instructional text.*

**PROTECTION OF HUMAN SUBJECTS**
*For additional guidance, refer to Section 5, titled “Human Subjects Research Policy,” from the* [*Supplemental Grant Application Instructions for All Competing Applications and Progress Reports*](http://grants.nih.gov/sites/default/files/supplementalinstructions.docx)*, which was issued by the US Department of Health and Human Services. Also, refer to the* [*Required Education of Key Personnel on the Protection of Human Subject Participants*](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-054.html)requirement as you complete this section. *Do not exceed five pages.*

*Describe the protection of human subjects involved in your research.*

**Estimated Final Racial/Ethnic and Gender Enrollment Table**

|  |  |  |  |
| --- | --- | --- | --- |
| **Race** | **Male (N)** | **Female (N)** | **Total (N)** |
| American Indian/Alaska Native |  |  |  |
| Asian |  |  |  |
| Black/African American |  |  |  |
| Hawaiian/Pacific Islander |  |  |  |
| White |  |  |  |
| Multirace |  |  |  |
| **Ethnicity** | **Male (N)** | **Female (N)** | **Total (N)** |
| Hispanic (Latino/Latina) |  |  |  |
| Non-Hispanic |  |  |  |

**REFERENCES CITED**

*Do not exceed 10 pages.*

*Follow scholarly citation practice and list the source material cited in your Research Plan. PCORI suggests using American Medical Association citation style, but other citation styles are accepted.*