# Pilot Award in Prematurity Research

Project Award Amount: Up to \$50,000 over one year



Being born prematurely is the leading cause of death for children under 5, worldwide, and preterm babies who do survive often face a lifetime of health complications. Unlike other high-income countries, rates of preterm birth are on the rise in the US, particularly among women of color. Preterm birth is an epidemic and in part a reflection of systemic inequities Black and Brown women in the US face.

The California Preterm Birth Initiative is working to reduce preterm birth rates, address racial disparities, and improve birth outcomes for preterm babies. Our research is place-based, holistic, and considers social mechanisms hand in hand with biological factors. The Initiative conducts and funds research across the life course (preconception, prenatal, and postnatal) in collaboration with communities in Fresno, Oakland and San Francisco.

The California Preterm Birth Initiative is currently seeking highly innovative research proposals which meet the following criteria:

#### **Outcomes:**

Research proposals should have strong potential to reduce preterm birth rates, disparities, and/or improve birth outcomes for babies born prematurely, especially in our communities of focus in Fresno, Oakland and San Francisco.

### Four Research Aims:

Initiative's four research aims:

1. Discovery

Focus:

- 2. Interventions across the reproductive lifecourse
- Collective Impact (multi-sector, place-based efforts) and Policy
- Communication, Collaboration and Capacity Building (disseminating knowledge and building capacity).

Research proposals should be aligned with one or more of the

Successful applications will demonstrate transdisciplinary (or multi-sector) collaboration, a health equity focus, and community involvement in the planning and/or performance of the project. For this cycle, all applications that address compelling

For this cycle, all applications that address compelling research questions within any of the four <u>PTBi-CA aims</u> will be considered, with emphasis given to <u>priority topics</u> identified by our communities.

For more information, please watch these short videos About the Preterm Birth Initiative and how we Partner with Community Members to prioritize research for funding.

#### **Avoiding Redundancy:**

PTBi-CA encourages potential applicants to review our <u>funded</u> <u>research</u>. We intend to supplement our current portfolio to achieve synergy and avoid redundancy where possible. We discourage proposals in the following categories:

- Preterm birth risk communication
- Research focused on air pollution unless focused on interventions to reduce exposures

For more information about PTBi-CA, examples of highly responsive proposals, and Innovation Award application instructions, please use the following links...

#### **Eligibility**

**<u>Eligibility requirements</u>** must be met at the time of submission. No waivers will be accepted.

## All projects require the participation of a UCSF Co-Investigator:

- UCSF Faculty in any series, including adjunct and professional research series, and at all ranks: Instructors, Assistant Professors, Associate Professors, Professors can apply.
- Non-faculty Specialists can apply.
- Residents, Post-Doctoral Fellows, Clinical Fellows, clinical and staff research scientists, can also apply.

Researchers with the following affiliations are encouraged to apply:

- UCSF-affiliates
- Benioff Children's Hospital Oakland (BCHO) Researchers: all research, hospital-based, clinical and staff scientists at any level (including postdoctoral fellows), including those affiliated with the Children's Hospital Oakland Research Institute (CHORI).
- UCSF Fresno Researchers: all affiliated researchers including faculty in any professional research series, fellows, research scientists and emeritus faculty.

Research teams outside of UCSF and/or community-based investigators in one of our three target geographies are encouraged to contact PTBiCalifornia@ucsf.edu to be matched with an interested collaborating UCSF co-investigator.

#### **Terms of the Award**

- 1. PTBi-CA is committed to building capacity among researchers and community stakeholders to engage in collaborative transdisciplinary work and the dissemination of new ideas. Awardees are required to attend up to two meetings to encourage the cross-fertilization of ideas that spark new transdisciplinary, cross-sector partnerships (which may lead to further funding opportunities). Grantees are also encouraged to attend other PTBi-CA-sponsored networking opportunities that foster innovation and collaboration, including our monthly Collaboratory series.
- 2. All investigators who enroll human subjects must include a plan to disseminate their research results to the project participants and the broader community.
- 3. All studies involving human participants will require approval by or exemption from the UCSF Committee on Human Research (CHR) as well as evidence of IRB approval from other institutions involved in the project (as appropriate) within three months of receiving their award letter. Studies involving research on live animals or on tissues collected from live animals will require approval from the UCSF Institutional Animal Care and Use Committee (IACUC) within three months of receiving their award letter. If a project is selected for funding, proof of CHR or IACUC approval must be supplied before funds can be released.
- 4. Investigators seeking funding for biospecimen testing will be asked to submit a data-sharing plan that will allow the sharing of individual-level biomarker/-omic data (without identifiers) through collaborative agreements after the initial publication of results (see #5e below in Application Instructions).
- 5. PTBi-CA actively encourages the publication of results from all work, including those that do not find an association or effect. All publications and presentations resulting from the research funded by PTBi-CA must be acknowledged as: This research was supported by the UCSF California Preterm Birth Initiative, funded by Marc and Lynne Benioff.

#### **Evaluation of Applications and Criteria for Review**

Applications that are complete and meet eligibility requirements will be evaluated by three committees: the PTBi-CA Community Advisory Board (CAB), a UCSF scientific review committee, and the PTBi-CA leadership team. PTBi-CA will make the final funding decisions after considering the CAB and scientific reviews and the alignment of the highest quality proposals with our stated goals and current research portfolio.

#### **Community Advisory Board Review**

PTBi-CA pursues holistic, place-based and community-engaged research. We are committed to partnering with community stakeholders throughout our efforts, and have convened a Community Advisory Board (CAB) comprised of:

- Community members who have experienced preterm birth, are at-risk for preterm birth, and/or who have family members affected by preterm birth
- Clinic- or hospital-based providers of women at risk for preterm birth or babies born preterm
- Community-based service providers serving communities with high rates of preterm birth
- Current or former preterm birth-related research study participants

CAB members evaluate submitted proposals based on the scientific abstract, and a **plain language summary** detailing the project's background and history of the work, scope, community-engagement efforts and impact (see #3 below in Application Instructions), with access to the full proposal upon request. **It is essential that applicants develop a plain language summary that is clear, engaging, and written specifically for a general, lay audience.** Please note that CAB review is a significant component of the review process. CAB review criteria include:

- 1. **Impact:** Will the study answer questions that are important to women of reproductive age and their families in San Francisco, Oakland, or Fresno?
- 2. **Partnership:** Does the application demonstrate engagement and involvement of community members or community-based organizations in the planning and/or performance/review of the study?
- 3. **Dissemination:** Is the plan to disseminate study results to the project participants (and broader community, if applicable) appropriate and effective?

For more information about crafting a compelling summary for the Community Advisory Board review, visit the <a href="PTBi-CA website">PTBi-CA website</a>.

#### **Scientific Review**

Applications will be evaluated for scientific and technical merit by a review committee convened by the UCSF Resource Allocation Program (RAP) and assigned an overall score, in accordance with specific PTBi-CA review criteria:

- 1. **Scope:** Does the project address the research priorities outlined in the RFA?
- 2. **Impact:** Will the project lead to improvements in the prematurity research field for the populations and geographies of focus?
- 3. Approach/Innovation: Is the research question and proposed design appropriate for the project scope and timeline? Is the proposal novel or innovative?
- **4. Investigative team:** Does the proposed team include members who are experienced in areas that are directly related to the proposed project?
- 5. Transdisciplinarity: To what degree does the project use a transdisciplinary approach, including engagement with the community? A transdisciplinary team with differing areas of professional and community-based expertise is encouraged.
- 6. Institutional support: Does the project have the support of the departments and/or organizations involved?
- 7. **Budget:** Is the budget appropriate for the project scope and timeline?

#### **Informational Webinar**

PTBi-CA will host two informational webinars for applicants interested in speaking with members of the Community Advisory Board about their proposed projects and **plain language summaries**. This is an opportunity for applicants to receive feedback about study protocols, recruitment strategies, dissemination plans, and mechanisms for community engagement. The webinars will be held from **12:00 – 1:00pm** on **Tuesday, February 11th and Wednesday, February 19th, 2020. Please register here.** 

#### **Application Instructions**

STEP 1 Complete the electronic application form

**STEP 2** Upload your proposal as a single PDF that includes each item listed in numeric order in the instructions below. Do not include form fields in your PDF document.

Proposal Length: Maximum 6 pages, including figures and tables, excluding table of contents and literature cited.

Format Requirements: Arial font; 11 pt; minimum 0.5 inch for all margins; no appendices; include page numbers and table of contents.

#### Resubmissions

**Definition:** same research topic with an amended application or research plan rather than a new research topic and new research plan. **Requirements:** Please use up to one extra page to introduce your revised proposal, addressing the issues raised in the review, and any additional changes to your proposal. A new letter from the Chair is not required if the resubmission is within 2 cycles (one skipped cycle max). Please include the old letter and state your resubmission is within 2 cycles and that a new letter is not required. Make sure the new changes are highlighted in bold or italic font so the reviewers can easily see where and how the proposal has changed. Do not use track changes.

#### Please include the following items in your single PDF:

- 1. **Principal Investigator and Co-Investigator information:** Name(s), position, institutional affiliation. **NOTE:** Only one application as PI (PI1 or PI2) is permitted per cycle, for awards of any length (e.g., the same investigator may not serve as PI on both a one year and a two year application in the same cycle).
- 2. Project Title
- 3. Plain Language Summary for the Community Advisory Board (1 page max): Please provide the following information for the PTBi-CA CAB. Of note, this section is the principal material that informs the CAB review and as such should be clear, engaging, and written specifically for a general audience. For more information about crafting a compelling summary for the CAB, please visit the PTBi-CA website.
  - a. Project background and history of the work
  - b. Project summary
  - c. Community engagement and dissemination plan: Please describe your community-engagement efforts to date around the proposed work. How has your research team assessed that this work is relevant to community members? What do you think the impact will be for the intended communities? Please describe any strategies for incentivizing study participation and retention, and your plans for disseminating results.

- 4. Scientific Abstract: The abstract (max. 300 words) should include a brief background, specific aims or objectives, methods, significance and relevance of the study for prematurity research in the target geographies and populations.
- 5. Research Proposal: Maximum 6 pages including figures and tables (excluding timeline, literature cited, budget and justification).
  - a. Aims: Two maximum
  - b. Background and rationale for study
  - c. Preliminary data
  - d. Existing infrastructure that will support the implementation of the proposed project
  - e. **Methods:** i) Hypothesis or research question; ii) research approach including details about subjects, methods, and analyses; iii) data sharing plan\*; and iv) a discussion of how the study may advance PTBi-CA's stated aims in the geographies and populations of focus.
    - \*All projects that yield biomarker or other -omic or molecular data must include a plan to make source individual level biomarker/-omic and diagnostic data (without identifiers) available to other investigators at UCSF and elsewhere through collaboration. Secondary projects that leverage source biomarker/-omic and diagnostic data may qualify for future project funding through PTBi-CA.
  - f. Human subjects: Describe the methods that will be used to protect subjects and protected Health Information (PHI)
  - g. Dissemination plan: please include a plan to present results to study participants (and a broader community, if applicable).
- 6. Timeline table: Include 6-month milestones for each aim, recommended 1 page.
- 7. Literature cited: Recommended <3 pages.
- 8. **Detailed budget:** Up to \$50,000 over one year, recommended 1 page. For investigators located outside of San Francisco, please allocate up to \$2,000 for travel expenses to PTBi-CA meetings.

	Allowable	Not Allowable
PI Salary*	X	
Co-I Salary	X	
Postdoctoral Trainee Salary (if applicable)	X	
Other Staff Support	X	
Supplies	X	
Equipment	X	
Software	X	
Computers	X	
Mailing	X	
Tuition		x
Travel (domestic for project)	X	
Research Staff Support (e.g. RSA; Lab Technician)	X	
Patient Care	X	

<sup>\*</sup> NIH base salary cap. Generally PI partial salary support should not exceed 20% of the budget, anything over 20% must be well justified. Multiple PIs can decide how to distribute the 20% salary support among them (e.g., 10%/10% or 12%/8%, etc.). There is no limit on Co-I salary.

Note: Indirect Costs (up to 10% for non-UCSF investigators and partners) are allowed, however this amount must be included in the total allowable budget.

- 9. Budget Justification: Fully and clearly justify all costs, recommended 1-2 pages.
- 10. Biosketch of Principal Investigator(s) and Co-Investigator(s) and UCSF Faculty Mentor(s) (if applicable): (5 page maximum); academic applicants must use this form Biosketch Version E. Include biosketches for all Pls of a multi-Pl application, and any other key personnel such as Co-Investigator(s) or UCSF Faculty Mentor(s). In section "D. Additional Information", list the relevant recent past, planned, active, and pending proposals, including percent effort and total direct costs (annual), where possible. Include a brief discussion of any potential overlap with the current proposal. Community-based investigators should include a detailed resume that covers employment and experience over the past 10 years.
- 11. Letter of commitment from PI and Co-Is: This/these letter(s) should outline the PI and Co-I roles, commitment to specific activities, and the proposed timeline.
- 12. Letter of support from Departmental Chair or other appropriate person (for PIs based at UCSF); institutional letter of support (for PIs not based at UCSF). The letter should comment on the independence of the applicant and availability of space and other resources to support the implementation of the proposed research. If there are multiple PIs, a letter of support is required for each PI. If PIs are in the same department, the chair can write a single letter on behalf of both PIs.

