1. **Background:** This program seeks to support the development of studies with potential for future extramural funding, and is designed to enhance or encourage new precision medicine research programs.

2. **Funding Source and Amount:** Funding for the 2018 HLVI Near Horizons Precision Medicine in Cardiovascular and Pulmonary Research Grant program is derived from the UC Heart, Lung and Vascular Institute, UC Health and the Division of Cardiovascular Health and Disease. The successful application will receive a maximum of $25,000 for the 2018 New Horizons. Project period: April 2, 2018 – April 1, 2019. A Progress report will be requested at the end of the project. The grant should be acknowledged in all relevant publications.

**Precision Medicine (PM):** PM is an emerging field that proposes the customization of healthcare, with medical decisions, practices, or products tailored to the genes, environment, and/or lifestyle of individual patients. For example, genetic-linked cardiovascular diseases such as Marfan’s syndrome, bicuspid aortic valve, calcific aortic valve disease, cardiac arrhythmias, cardiomyopathies, atrial or ventricular septal defects, familial hypobetalipoproteinemia, and severe hypercholesterolemia are targets of some of the most promising PM approaches available today. These diseases usually come about through the gradual accumulation of genetic changes in genes that control cell growth. These genetic profiles can be used in a number of ways to help doctors choose the best treatments for each individual patient. PM approaches consider proper medication doses to maximize efficacy and minimize side effects, interactions with other drugs patients may be taking, as well as factors from the environment, such as diet and exposure to toxins.

A research study is responsive to the RFA if it:
   i. Proposes the customization of healthcare, with featured PM decisions, practices, or products tailored to an individual patient; or
   ii. Relates to the development or advancement of tools, including molecular diagnostics, imaging, and analytics; or
   iii. Proposes the design of new tools for building, analyzing, and sharing large sets of medical data

3. **Project priorities:** To be considered, a proposal must focus on important problems
in the field of cardiovascular or pulmonary PM. A wide spectrum of projects can be considered relevant. Priority will be given to those projects that carry the highest potential for a major advancement and are most likely to lead to a successful application for extramural funding, as well as projects with well-developed concepts where additional data are required for proposal submission and where innovative ideas require additional testing. The strategy for advancement of the research project for subsequent submission of an NIH proposal or similar application should be described clearly.

4. **Collaborations:** The HLVI Near Horizons Grant program encourages applications that include interactions between clinicians and researchers to foster the development of investigations for patients with serious diseases and chronic illnesses. Interdisciplinary studies that include participation of researchers from other UC colleges, divisions and affiliates are encouraged. Active collaborations with co-Investigators from other UC Colleges, divisions, departments or affiliated entities, such as Cincinnati Children’s Hospital Medical Center or the Cincinnati Veterans Affairs Medical Center are encouraged. Clinical and postdoctoral fellows should include a co-investigator with appropriate research expertise.

5. **Eligibility:** In order to be eligible for these funds, the Principal Investigator on the application must either hold a full-time faculty appointment at the UC College of Medicine, in a department or division currently participating in the Heart, Lung and Vascular Institute - specifically, Cardiovascular Health and Disease; Pulmonary Critical Care and Sleep Medicine; or Vascular Surgery.

6. **Letters of support:** Applicants should include a letter from their supervisor, Division Chief or Chair as part of the application. Dedicated time to complete the project should be secured and included as a cost share in the budget.

7. **Overview of Review Process:** The review of applications is performed in three phases: (1) Letter of Intent (LOI), (2) Application/Scientific Review, and (3) Administrative Review. During the first phase, the LOIs will be scored and ranked, and the top applicants will be invited to submit formal 3-page applications. No critiques will be provided to applicants at the LOI phase. During the second phase, the 3-page applications will be reviewed by 2-3 independent scientific reviewers serving on an ad hoc HLVI review committee. The ad hoc HLVI review committee will meet and discuss applications similar to an NIH study section, and members present for the discussion will score each application. During the third and final phase, the applicant rankings will be reviewed by the HLVI Leadership, and awards will be granted. Collaborative applications will be given priority during this administrative review. Critiques from the second phase of the review will be provided to the applicants after awards are announced.

8. **Letter of intent (LOI):** The LOI consists of the application face page and 1 page describing the hypothesis and 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 exert on clinical care. Provide a brief description of the research design and methods. Also, include a sentence or two describing the responsiveness to the RFA and how the proposal will lead to
extramural funding, including the projected date and target of the application. Use NIH margins and font requirements. In addition, applicant PIs who have received research support from the HLVI in previous years should include an additional brief report (< 1 page) summarizing progress toward extramural grant submission. PLEASE NOTE: LOIs must be submitted via CCAPS; which will be available by December 15, 2017. The LOI must be received before midnight on January 5, 2018.

9. **Application Deadline:** Those who have submitted LOIs that are selected to advance to the application stage will receive an invitation from HLVI Leadership to submit a 3-page application. Applications will be invited on Jan 19, 2018. All applications must be submitted on the CCAPS System. Applications must be received before midnight on **February 16, 2018.** Applications received after the deadline will be considered non-responsive and will not be reviewed.

10. **Composition of Applications:** Research proposals require the following elements in the order specified:
   
i. Face page (check all appropriate IBC, IACUC, IRB, or Radiation Safety approvals or indicate pending if submitted)
   
   ii. Abstracts (scientific and lay)
   
   iii. Detailed Budget (1 year; use PHS 398 form provided)
   
   iv. Budget justification
   
   v. Biosketch(es) (include PI and co-investigators; use PHS 398 form)
   
   vi. Other support (PHS 398 form)
   
   vii. Hypothesis and Specific Aims (1 page)
   
   viii. Background and Significance
   
   ix. Preliminary Results
   
   x. Research Design and Methods
   
   xi. Statements regarding human subjects and/or animals
   
   xii. Literature cited
   
   xiii. Consortium/Contractual Arrangements
   
   xiv. Letters of support from the PI’s department head and collaborators or consultants

   **NOTE:** ITEMS viii-xi LISTED ABOVE MUST NOT EXCEED 3 PAGES
# 2018 HLVI Near Horizons Precision Medicine Research Grant

## UC HLVI Near Horizons Precision Medicine Grant - Application Face Page

### 1. TITLE OF PROJECT

*Do not exceed 56 characters, including spaces and punctuation.*

### 2. PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR

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<thead>
<tr>
<th>2a. NAME (Last, first, middle)</th>
<th>2b. DEGREE(S)</th>
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<tr>
<th>2c. POSITION TITLE</th>
<th>2d. PRINCIPAL INVESTIGATOR’S MAILING ADDRESS</th>
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<th>2e. DEPARTMENT</th>
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<th>2g. TELEPHONE (Area code, number and extension)</th>
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### 3. CO-INVESTIGATOR

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<th>3c. POSITION TITLE</th>
<th>3d. OTHER CO-INVESTIGATORS</th>
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<td>(PLEASE PROVIDE INFORMATION AS IN SECTIONS 3A TO 3G; IF MORE THAN 2 CO- INVESTIGATORS, USE BOTTOM OF THIS FORM TO SUPPLY THE INFORMATION)</td>
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### 4. Human Subjects Research

- ☐ No ☑ Yes

4a. Research Exempt

If “Yes,” Exemption No.

4b. Human Subjects Assurance No.

4c. NIH-Defined Phase I Clinical Trial ☐ No ☑ Yes

### 5. Human Subjects Protection Certification

- ☐ No ☑ Yes

### 6. Vertebrate Animals

- ☐ No ☑ Yes

6a. If “Yes,” IACUC Approval Date:


### 7. IBC Protocol

- ☐ No ☑ Yes

7a. If “Yes,” Approval Date: 7b. Approval Number:

### 8. Radiation

- ☐ No ☑ Yes

8a. If “Yes,” Approval Date:

### 9. DATES OF PROPOSED PERIOD OF SUPPORT

*month, day, year—MM/DD/YY*

From April 2, 2018 Through April 1, 2019

### 10. COSTS REQUESTED

*Direct Costs ($) ONLY*