Appendix A

**Excerpts from the Pediatric Heart Network Program Announcement: PHN Scholar Award**

**2021-2022**

**Part 1. Overview Information**

The Pediatric Heart Network Scholars Program will award study grants to support outstanding researchers in the field of translational, clinical, health services, or epidemiological pediatric cardiovascular disease or adult congenital heart disease. Application in the basic science fields will ***not*** be considered. Proposals related to existing or planned (full, pilot, or ancillary) PHN studies are encouraged, but not required. Collaborative proposals involving multiple PHN centers are also encouraged. However, proposals should be related to an area of PHN interest or investigation.

Diversity, Equity, Inclusion

Applicants and applications must consider diversity, equity and inclusion (DEI) and describe how DEI will be addressed under this specific heading in the application. For example, an applicant could study DEI as part of their proposal or DEI could be considered in the various aspects of the application (see Research Plan below). Reviewers will evaluate and score this as part of the review process. Candidates from underrepresented racial, ethnic, economically or geographically disadvantaged groups or those with a disability are encouraged to apply.

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| **Participating Organization(s)** | National Institutes of Health (NIH) |
| **Components of Participating Organizations** | National Heart, Lung, and Blood Institute’s (NHLBI) Pediatric Heart Network (PHN) |
| **Funding Opportunity Title** | PHN Scholar Awards |
| **Number of Applications** | Up to 18 applications will be reviewedLimited to 2 applications per PHN Core Center |
| **Funding Opportunity Purpose** | The PHN encourages candidates to develop innovative research applications for translational, clinical, health services, or epidemiological pediatric cardiovascular or adult congenital heart disease research. These may be new pilot studies or ancillary studies related to existing or planned PHN studies. This opportunity will provide a stepping stone for junior faculty (MD or PhD within 5 years of completion of their last fellowship at the time of funding), categorical fellows (at the time of funding) and post-categorical fellows accepted in advanced training subspecialty programs and pre-doctoral/doctoral nurses already undertaking research, who are intending to pursue formal research training or research funding. |

**Key Dates *(will be further refined)***

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| **Posted Date** | September 1st 2021 |
| **Internal Scientific Merit Review of Brief Proposal\*** | September 1st through October 29th, 2021 |
| **Letter of Intent Due** | October 29th, 2021  |
| **External Application Due**  | February 7th 2022 |
| **External Scientific Merit Review of Detailed Proposal** | February 7th – February 28th, 2022 |
| **Notice of Awards** | Mid-March  |
| **Research Concept Presentation by 2022 Scholars** | PHN Steering Meeting (April 20th-23rd, 2022) |
| **Earliest Start Date** | July 1, 2022 |

**\*Within Core PHN Center**

**Part 1. Full Text of Announcement**

**Section I. Funding Opportunity Description**

The PHN encourages candidates to develop innovative research applications for translational, clinical, health services, or epidemiological pediatric cardiovascular research or adult congenital heart disease. These may be new pilot studies or ancillary studies related to existing or planned PHN studies. This opportunity will provide a stepping stone for junior faculty (MD or PhD within 5 years of completion of their last fellowship at the time of funding), categorical fellows (at the time of funding) and post-categorical fellows accepted in advanced training subspecialty programs, and pre-doctoral/doctoral nurses already undertaking research, who are intending to pursue formal research training or research funding.

**Research Objectives**

To support junior investigators in the field of pediatric cardiovascular research or adult congenital heart disease and assist their development into future independent clinician scientists with an awareness of the need to address DEI in the development and implementation of research proposals.

**Section IV. Application and Submission Information**

1. **Content and Form of Application Submission**

Candidates must use the Informational Table/Disclosures form and follow all specifications provided in the Applications document. A checklist for complete applications is provided on the last page of the Applications document.

It is critical that candidates follow the instructions for the attached PHN Scholars Application. Applications that are out of compliance with these instructions will **NOT** be accepted for review.

1. **Required Components**

All candidates must utilize the attached PHN Scholars Application form. Complete applications must contain the following components:

* Biosketch of the Candidate in the *new* NIH format (https://grants.nih.gov/grants/forms/biosketch.htm)
* Biosketch of the Mentoring PI in the *new* NIH format. ***Do not*** include additional Biosketches. If additional Biosketches are submitted, the application will not be reviewed.
* Letter of Support from the PHN Center Corresponding PI. If a co-investigator is the PHN Center Corresponding PI, the letter should be from one of the other PHN Center PIs. If both center PIs are involved, the letter should be from either the Division Chief or the Department Chair. ***Do not*** include additional Letters of Support. If additional letters are submitted, the application will not be reviewed.
* Informational Table/Disclosures
* Proposal with the required contents and specifications for submission, including the newly created section on Diversity, Equity and Inclusion.
* References
1. **Page Limitations and Research Plan Component**

Details regarding the preparation of each section and the page restrictions for each section are provided directly on the PHN Scholars Applications Document. The Informational Table/Disclosures at the beginning of the Proposal and the References do not count toward page limits.

1. **Submission Dates and Times**

Up to 2 applications may be submitted from each PHN Core Center. All candidates will be notified of funding decisions prior to the Spring 2022 PHN Steering Committee Meeting (*see Key Dates, above*)

**Section V. Application Review Information**

1. **Criteria**

The review criteria are adapted from the NHLBI K23 Award program and described below. All applications submitted to the PHN are evaluated for scientific merit.

**Scored Review Criteria**

Applications will be reviewed and scored using modified NIH K-award criteria as indicated below. It is important to remember that not all bullets will be applicable to all applications--they are examples of what the reviewers will consider strengths. An application may not be strong in all areas but receive a favorable overall score if there is sufficient strength in other areas.

Research Plan

* Does the project address an important problem in pediatric cardiovascular disease or adult congenital heart disease research?
* Is the project aligned with the mission of the Pediatric Heart Network?
* How will scientific knowledge, technical capability, and/or clinical practice be improved?
* Are the proposed research questions, design, methodology, and statistical analyses well-reasoned and appropriate to accomplish the Specific Aims of the project?
* Are the proposed aims and procedures relevant to the study design and hypothesis?
* Does the research identify a clinically relevant and feasible primary study endpoint which is achievable within the proposed timeline for the study?
* Is there a strong scientific premise for the project?
* Has the candidate presented strategies to a well-reasoned, robust, unbiased and appropriate approach for the work proposed?
* Is the research plan appropriate to the candidate's stage of research development and as a vehicle for developing the research skills described in the career development plan?
* Have the investigators demonstrated that the patient populations are of sufficient size and will be available?
* Have the investigators demonstrated that funds are adequate and available for proper conduct of the study?

Candidate and Career Development Plans

* Does the candidate have the potential to develop as an independent and productive researcher?
* Are the candidate's prior training and research experience appropriate for this award?
* Is the candidate’s academic and research record of high quality?
* What is the likelihood that the plan will contribute substantially to the scientific development of the candidate?
* Is the candidate engaging in local learning opportunities which are critical aspects to a research career?
* Does the candidate’s plan include DEI training?
* Does the Letter of Support address the above review criteria?
* Does the Letter of Support provide evidence that the candidate has a high potential for becoming an independent investigator?

Diversity, Equity, and Inclusion (DEI)

* Does the research address diversity, access, or health inequities?
* Does the research include recruiting strategies to include diverse participants?
* Does a study/trial include a clear DEI plan to identify underrepresented groups within the potential study population and facilitate their enrollment or explain why this is not feasible? For example, are there important racial, ethnic and social determinants (geography, transportation issues, education, language barriers, etc.) that impact enrollment? If so, are there mechanisms whereby these limitations will be addressed?
* Are underrepresented groups identified and justified as being underrepresented?

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| * Does the research investigate systemic barriers to providing optimal care and strategies to overcome them?
* Are race, sex, gender, and social/economic/geographic variables considered potential determinants in outcomes?
* Are parents or community leaders from underrepresented groups included in the research planning/team, if appropriate?
* Does the environment in which the work will be done address DEI?
* Is there a plan to disseminate the results to underrepresented groups?
* Is the candidate or mentoring PI a member of a DEI group addressing issues on a local or national level?
* Describe DEI within the research team.
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Mentor(s) and Collaborators

* Is the mentoring team appropriate to ensure all facets of the study will be strong? For example, sometimes a solid mentoring team includes a statistician, methodologist or ancillary domain, in addition to the person who is the topical expert.
* Is there an adequate description of the roles of the mentoring team, and how they will interact with the candidate? Is the Mentoring PI identified?
* Is there evidence of the mentor’s, consultant’s, and/or collaborator’s previous experience in fostering the development of independent investigators?
* Is there evidence of the mentors’ current research productivity and peer-reviewed support?
* Have the mentors demonstrated contributions to the success of the PHN?
* Does the mentoring team include underrepresented groups, as appropriate?

Institutional and PHN Environment

* Will the environment in which the work will be done contribute to the probability of success?
* Will the project benefit from the unique features of the PHN?
* Is there evidence that the institution will provide sufficient protected time for the project to be carried out?
* Is the institutional commitment to the career development of the candidate strong as demonstrated in the Letter of Support?

Appendix B

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# PHN Scholar Award

# 2021-2022 Application

The complete application must include:

1. Biosketch of the Candidate in the new NIH format.
2. Biosketch of the Mentoring PI in the new NIH format. Do ***not*** include additional Biosketches.
3. Letter of Support from the PHN Center Corresponding PI. If the PHN Center Corresponding PI is a co-investigator, the Letter of Support should be from one of the other PHN Center PIs. If both center PIs are investigators, the letter should come from the Division Chief or Department Chair. Do ***not*** include additional Letters of Support.
4. Informational Table/Disclosures
5. Proposal with the required contents and specifications for submission.
6. References

**Instructions for the Proposal** (maximum, 11 pages)

1. The proposal must **not** exceed 11 single-spaced pages (11 pt Arial—Arial narrow is ***not*** permitted) as described below. The Specific Aims section must **not** exceed one page. The rest of the application must be no more than 10 pages. The page limits next to the content descriptions below are suggestions (except the Specific Aims page), the authors may format the application as they see fit within the page limits as above. The Informational Table and Disclosures should be placed at the beginning of the Proposal. Include disclosure of any significant financial interest(s) that might be related to the proposed area of research. The Informational Table/Disclosures and the References do not count toward page limits. **No** appendices are allowed. Incomplete applications and applications that fail to comply with these instructions will ***not*** be reviewed.

**Required content for the Proposal** is as follows:

1. Specific Aims (1 page): State a brief background, the goals of the proposed research, specific objectives (and hypotheses, if applicable), and summarize the expected outcome(s), including the impact of the results of the proposed research on the research field(s) involved.
2. *Candidate’s Background (1/2 to 1 page):* Describe your research background, indicating how the award fits into past and future research career development.
3. *Career Goals and Objectives (1/4 to 1/2 page):* Describe your short-term and long-term career goals. Describe how the career development award will enable you to develop and/or expand your research career. Describe local opportunities that will be leveraged to advance your research career. You are encouraged to include a timeline, including plans to apply for subsequent grant support.
4. *Mentors (1/4 to 1/2 page)*: Describe the expertise, role and how each member of the mentoring team will interact with the candidate. Demonstrate the Mentoring PI’s previous experience in fostering the development of independent investigators and current research productivity.
5. *Project fit with the PHN mission and unique PHN environment (1/4 page):* Describe the contributions the mentors have made to the success of the PHN. Describe how the project fits with the mission of the PHN and how the unique aspects of the PHN will be leveraged to accomplish the proposed research and/or the research career development of the candidate.
6. *Research Plan (5-7 1/2 pages):*
	1. **Significance:**
		1. Explain the importance of the problem that the proposed project addresses.
		2. Describe the scientific premise and rationale for the proposed project.
		3. Preliminary studies are not required, but if they exist, they should be described here.
	2. **Approach:**This section must address all of the following:
		1. *Study/Trial Design:* Include a brief overview of the study design, consider including a study schematic diagram. Describe procedures to minimize bias if relevant. List outcome measures. If applicable, provide a schedule of measurements and visits.
		2. *Selection of subjects*: Describe inclusion and exclusion criteria, data regarding subject availability, and an estimate of the accrual period. List participating institutions for pilot studies and collaborating institutions, if relevant.
		3. *Treatments:* If applicable, describe the treatments to be administered. Treatments can include drugs, biologics, surgery, devices or diagnostic procedures. Describe the regulatory (e.g. FDA; Health Canada) status of the proposed treatment, if applicable.
		4. *Protection of Human Subjects, Safety Considerations and Assessments.* Provide an attestation of training in the Responsible Conduct of Research (RCR) for human subjects’ research for all investigators.
		5. *Statistics:* Include a sample size calculation as well as a preliminary analysis plan. For Phase III trials and other studies where power calculations are appropriate, calculate sample sizes based on a minimum of 85% power. Assumptions used for the calculation of target sample size should be provided, including but not limited to the Type I and II error rates and the detectable effect size.
		6. *Limitations/Potential problems, Alternative Strategies, and Benchmarks for Success*
7. *Diversity, Equity, Inclusion (DEI, 1 page or less):* Explain how this application addresses the values of DEI. DEI can be addressed in career goals/objectives, research environment, research approach, the research team, and/or other areas of the application.
8. *Budget (1/4 page or less):* Include a general description of budget items and an estimate of the costs.
9. *References (not included in the total 11-page limit)*

Questions may be directed to your Center’s PHN Scholarship Committee Representative or one of the Committee Chairs: LuAnn Minich at L.Minich@hsc.utah.edu or Lara Shekerdemian at lssheker@texaschildrens.org).

**Please submit completed applications electronically to the PHN Mailbox at** phnmailbox@healthcore.com**, by midnight EST Monday, February 7th, 2022. No late applications will be accepted.**

Appendix C

PHN Scholar Award

Reviewer Critique

Candidate:

Mentoring PI:

# Overall Impact

Reviewers will provide an Overall Impact Score to reflect their assessment of the scientific merit of the project and of the potential for the candidate to exert a sustained, powerful influence on the research field(s) involved. The following 5 scored review criteria, and additional review criteria should be considered. The overall impact score is NOT intended to be a mean of the 5 categories but rather reflects the overall quality of the application. An application does not need to be strong in all categories for the applicant to be judged as likely to succeed as an academic pediatric cardiovascular specialist.

Applicants should be rated on a 9-point scale (score 1-9). A score of 1 is an exceptionally strong application with essentially no weaknesses; whereas, a score of 9 indicates serious and substantive weaknesses with very few strengths. A score of 5 is considered average.

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| ***Overall Impact Score \_\_\_.*** *Write a paragraph summarizing the factors that informed your Overall Impact Score. Include strengths and weaknesses. These strengths and weaknesses should justify your Overall Impact Score.* |
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# Scored Review Criteria

Reviewers will consider each of the 6 review criteria below in the determination of scientific and technical merit, and give a separate score for each on a 9-point scale (score 1-9).

1. Significance

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| ***Significance score \_\_\_.*** Does the project address an important problem in congenital or pediatric acquired heart disease research and the mission of the Pediatric Heart Network? Is there a strong scientific premise for the project? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field? |
| **Strengths** **Weaknesses** |

1. Mentors

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| * ***Mentors score \_\_\_.*** Are the mentors/collaborators well suited to the project? Is the mentoring team appropriate to ensure all facets of the study will be strong? Do they have appropriate experience and training and well-defined roles for the protocol and for mentoring? Is there evidence of the mentors’ current research productivity and peer-reviewed support? Have the mentors demonstrated contributions to the success of the PHN? Is there evidence for prior success of the Mentoring PI in fostering the development of independent investigators?
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| **Strengths** **Weaknesses** |

1. Approach

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| ***Approach score \_\_\_.*** Are the overall strategy, methodology, and analyses well-reasoned, robust, unbiased and appropriate to accomplish the Specific Aims of the project? Have the investigators demonstrated that the patient populations are of sufficient size and will be available? Are the requested funds adequate for proper conduct of the study? Does the research identify a clinically relevant and feasible primary study endpoint which is achievable within the proposed timeline for the study? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?  |
| **Strengths****Weaknesses** |

1. Environment

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| ***Environment score \_\_\_.*** Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Is there evidence that the institution will provide sufficient protected time for the project to be carried out? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements? Is it clear how the structure of the PHN will be used to accomplish the Aims of the project? Does the Letter of Support assure the Division or Department will cover travel costs (including the person responsible for approving these costs) to a minimum of two PHN Steering Committee meetings as well as appropriate scientific conferences and meetings. |
| **Strengths****Weaknesses** |

1. Candidate and Career Development

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| * ***Candidate and Career Development score \_\_\_.*** Is the candidate advancing in the clinical skills required to pursue a successful career in their chosen subspecialty? Is the research plan appropriate to the candidate's stage of research development and as a vehicle for developing the research skills described in the career development plan? Is the candidate engaging in local learning opportunities which are critical aspects to an academic career? Has the candidate shown a commitment to an academic career as reflected by the personal statement of career goals? Does the Letter of Support address the above review criteria, and does it provide evidence that the candidate has a high potential for becoming an independent investigator? What is the likelihood that the plan will contribute substantially to the scientific development of the candidate?
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| **Strengths****Weaknesses** |

1. Diversity, Equity, Inclusion (DEI)

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| * ***DEI score \_\_\_.*** Does the research address diversity, access, or health inequities? Does the research include recruiting strategies to include diverse participants? Does a study/trial include a clear DEI plan to identify underrepresented groups within the potential study population and facilitate their enrollment? Is there diversity and inclusivity within the research team? Does the study identify important racial, ethnic and social determinants (geography, transportation issues, education, language barriers, etc.) that impact enrollment and describe the mechanisms whereby these limitations will be addressed? Does the research investigate systemic barriers to providing optimal care and strategies to overcome them? Are race, sex, gender, and social/economic/geographic variables considered potential determinants in outcomes? Are underrepresented groups identified and justified as being underrepresented? Are parents or community leaders from underrepresented groups included in the research planning and/or on the research team? Does the environment in which the work will be done address DEI? Is there a plan to disseminate the results to underrepresented groups? Is the candidate or mentoring PI a member of a DEI group addressing issues on a local or national level?
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| **Strengths****Weaknesses** |

**ADDITIONAL REVIEW CONSIDERATIONS:**

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| Protections for Human SubjectsHave the investigators provided strategies to protect human subjects from research risk relating to their participation according to the following five review criteria: (1) risk to subjects, (2) adequacy of protection against risks, (3) potential benefits to the subjects and others, (4) importance of the knowledge to be gained, and (5) data and safety monitoring for clinical trials\_\_\_\_\_Acceptable \_\_\_\_\_UnacceptableTraining in the Responsible Conduct of ResearchHave the investigators provided an attestation that all investigators have completed training in the Responsible Conduct of Research (RCR).\_\_\_\_\_Acceptable \_\_\_\_\_Unacceptable |

**ADDITIONAL COMMENTS TO THE CANDIDATE:**

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Appendix D

**PHN Scholar Award Review Process**

**2022**

1. All PHN Scholarship Committee members are expected to participate in the training, mock review, and scoring of all applications where they have no conflict.
2. Identify and recruit additional experts (if needed, as determined by the letters of interest).
3. Identify conflicts of interest (COI) and recuse reviewers from those applications. For applications where a reviewer has a COI:
	1. Reviewers will have no access to that application
	2. Reviewers will not be present during discussion of the application
	3. Reviewers will not score the application
4. Assign Primary and Secondary Reviewers to each application.
5. The Primary and Secondary Reviewers will critique the application and fill out the Critique Template. Preliminary scores should be assigned at this time.
6. All committee members should review all applications (if no COI) for sufficient familiarity with them to allow participation in the Discussion.
7. The statistician on the team will provide written comments regarding the statistical analysis plan (SAP) for all applications where there is no COI.
8. The ad hoc members with expertise in Diversity, Equity, and Inclusion (DEI) will provide written comments for the DEI section all applications where there is no COI.
9. The Primary Reviewer will provide his/her preliminary score, briefly summarize the application, and succinctly present the strengths and weaknesses. The identified strengths and weaknesses should clearly justify the score.
10. The Secondary Reviewer will provide their preliminary score and add any strengths and weaknesses that have not been identified by the Primary Reviewer. If the Secondary Reviewer disagrees with previous comments, these points should be clarified and discussed at this time.
11. The statistician will comment on the SAP.
12. The ad hoc reviewers will comment on DEI.
13. The remaining reviewers should participate in the Discussion to ensure clarity and obtain as much consensus as possible regarding the strengths and weakness of the application.
14. The Scientific Review Officer (SRO) will briefly summarize the strengths and weaknesses of the application.
15. The Chair will ask the Primary and Secondary Reviewers to provide a final score based on the Discussion.

1. All eligible reviewers will score the application based on their review and the Discussion. A score sheet for each application will be provided. Applications where the reviewer has a COI should be marked as such.
2. The Primary and Secondary Reviewers will make edits (if needed) to their comments to justify their final scores and submit their reviews to the SRO.
3. Scores will be reviewed, and funding determined by the NHLBI leadership.
4. The SRO will summarize the strengths and weaknesses of the application (including those identified by the Secondary Reviewer and the Discussion). This summary will be returned to the applicant as feedback regardless of the funding decision.

Appendix E

**Potential Diverse Patient Recruitment Strategies**

(as suggested by the Association for Black Cardiologists and the Food and Drug Administration)19,20

Engagement of diverse communities on clinical trial design

Collaborating with local advocacy groups and relevant medical associations to provide education on trial participation

Frequent and easily accessible recruitment events

Utilization of online recruitment strategies

Ensure that recruitment materials are at an appropriate health literacy level and are available in the predominant languages in that geographic area

Using technology to collect data to minimize the frequency of study visits

Engaging mobile medical professionals to visit participants in their communities

Providing verbal and written study information to patients in their primary language with easy access to interpreters

Considering financial reimbursement for travel expenses.