Request for Applications
2022-2023 PHEFREE Research Fellowship

Key Dates:
Date of RFA: November 23, 2021
Submission Due: January 7, 2022
Award Announced by: February 7, 2022
Funding Begins: September 1, 2022
Funding Ends: August 31, 2023 (may apply for a 2nd year of funding)

Scope of the Program
The primary mission of this program is to train and attract new investigators to research on hyperphenylalaninemia, biopterin defects and related conditions that is directly relevant to improvement in patient care, treatment and quality of life. Secondary goals are: 1) to increase the number of well-trained physicians and other health care providers to optimally manage patients with hyperphenylalaninemia disorders; 2) to contribute to the successful implementation of PHEFREE consortium site projects; and 3) to attract junior investigators to research on rare diseases in general.

The mechanism of this program is to add supplemental salary support to existing institutional support for the training of research fellows. Annual funding of up to $50,000 in direct support is available for partial support of 1 fellowship position. Indirect costs are allowed per the institution’s standard NIH rate agreement with the applicant’s institution. Application for successive 12-month periods of support is possible, but this will be on a competitive basis. The budget submitted does not need to be approved and signed off by the applicant’s institution unless the project is selected for funding. An applicant whose project is selected for funding will be asked to submit an official budget at the time the applicant’s selection is announced. The selected project will need to obtain any necessary IRB approvals before funds can be released.

One application can be submitted from each PHEFREE site or institution. Applicants and mentors who are not part of the PHEFREE Consortium are also eligible to apply. Applicants from non-PHEFREE sites, or from a PHEFREE site but with a primary mentor who is not affiliated with PHEFREE, should identify a PHEFREE investigator as a co-mentor. The Lead PI of the PHEFREE Career Enhancement Core can help facilitate identification of an appropriate co-mentor, if needed. Collaborations with other RDCRN consortia are actively encouraged; co-mentors should be identified from both consortia.

Research projects involving the use of animal models are not permitted by the parent RFA.

Trainees are expected to participate in the RDCRN career enhancement training program and to attend the annual Conference on Clinical Research for Rare Diseases (CCRRD). Travel costs to the annual conference ($1,500) should be included in the proposed budget.
Application Process: Graduate and postgraduate trainees, postdoctoral fellows, and junior faculty within 10 years from the completion of their degree/residency/clinical training are eligible.

Please submit a complete application. The full application should be submitted through the RDCRN grants portal as a PDF document (11 pt. Arial font, half-inch margins) and transmitted by 11:59 PM EST on January 7, 2022.

The application must include the following elements:

- Project title
- Project summary (page limit, half page)
- Project relevance to the overall mission of PHEFREE explaining how trainee activities will be integrated not only into the training mission but also the scientific and clinical mission of the PHEFREE Consortium (page limit, one page)
- Detailed Budget
- Budget Justification
- NIH biosketch of the applicant (please format according to the standard format https://grants.nih.gov/grants/forms/biosketch.htm)
- Applicant’s other support
- NIH biosketch of the mentor
- Career development plan that includes: (4 page limit)
  - Career goals and objectives (limit, half page)
  - Candidate’s previous research training and experience
  - Description of the research and career skills to be acquired, including a timeline and proposed deliverables (e.g., presentations, abstracts, manuscripts, grant applications, job applications).
  - Description of how this opportunity will help develop the applicant advance to the next stage of their career and support their long-term development in becoming an independent investigator. Applicants are encouraged to specifically describe how this opportunity will facilitate their continued involvement in rare disease research.
- Research strategy with the following sections (6 page limit)
  - Specific aims (limit, one page)
  - Background, Significance, Innovation, and Approach
  - A timeline of proposed research activities
- Mentoring plan that includes: (3 page limit, not including co-mentor letters)
  - Statement from the primary mentor describing how often the mentor and/or mentoring team will meet with the candidate and how the mentor(s) will provide guidance to the applicant for advancing to the next stage of their career (including, as appropriate, manuscript and abstract preparation, grant writing, job talks, teaching skills, mentoring skills, networking with other researchers)
  - A description of experience and track record of mentoring for each proposed mentor
  - Description of the facilities and training environment at the parent institution that will be available to the trainee.
  - Letters of support from all co-mentors
- Human Subjects Information (if applicable) that includes:
  - Protection of Human subjects (if applicable)
  - Recruitment and retention plan
  - Data Safety monitoring plan (if applicable)
  - Inclusion of women and minorities (if applicable)
  - Inclusion of children (if applicable)
- References cited
**Review criteria:** The review panel for the applications will consist of the PIs from 3-5 participating PHEFREE sites. External Ad Hoc reviewers may be called as needed. Applications will be scored using the NIH review criteria. The Chair of the review committee, Gerry Berry, MD will forward mean scores and recommendations for funding to the PI of PHEFREE. Each applicant will be reviewed based on the following criteria:

1) **Quality of the applicant and career development plan**
   a. Previous and current training
   b. Potential to contribute to the PHEFREE mission
   c. Commitment to research and patient care for PHEFREE conditions and other rare diseases
   d. Potential of the proposed career development plan to advance the applicant’s research and career goals
   e. Potential to become an independent clinical investigator

2) **Quality of research**
   a. Relevance to the overall mission of PHEFREE (applicants are encouraged to participate in/expand upon an existing PHEFREE project)
   b. Rare disease relevance
   c. For any research project meeting the [NIH definition of a clinical trial](https://grants.rarediseasesnetwork.org/grants/phefellow2022), projects will also be reviewed on the following:
      i. The extent to which the study design, sample size, statistical approach and planned analyses are appropriate for the proposed research question(s)
      ii. The adequacy of plans to standardize, assure quality of, and monitor adherence to the protocol and data collection activities.

3) **Quality of the mentoring plan and training environment and potential to become independent clinical investigator**
   a. Evidence of specific commitment by the mentor(s) to the applicant’s success
   b. Potential of proposed mentoring activities to facilitate achievement of the applicant’s research and career goals
   c. Adequacy of the institutional environment to support the applicant’s training needs

**Reporting and Sharing Outcomes:** Trainees are expected to publish results of data analysis projects/original projects and to present results to the PHEFREE Consortium at an in-person meeting or conference within a year of the grant funding period. Any research project that meets the [NIH definition of a clinical trial](https://grants.rarediseasesnetwork.org/grants/phefellow2022) will also be required to adhere to all NIH requirements for clinical trial registration and results reporting.

**Deadline for submission and funding dates:**
Deadline for submission is **January 7, 2022**. Awards will be announced by **February 7, 2022**. Funding will begin **September 1, 2022**. Any required IRB approvals need to be in place before funds can be released to the awardee.

The complete application should be submitted through the grants portal on the Rare Diseases Clinical Research Network (RDCRN) member website at [https://grants.rarediseasesnetwork.org/grants/phefellow2022](https://grants.rarediseasesnetwork.org/grants/phefellow2022). Members can log in to apply with their RDCRN accounts. If you are not a member of the RDCRN, you will need to log in using one of the methods on the login page. Please contact Hadley Morotti if you need assistance.

Please contact Dr. Berry or Ms. Morotti with any questions you may have about the application process.
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