PPN MENTORED DISASTER RESEARCH CAREER DEVELOPMENT AWARD (PDRCD)

Information and Instructions for 2023-2024 Application

THE PEDIATRIC PANDEMIC NETWORK (PPN)

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I. Introduction: Health Resources & Services Administration

Regional Pediatric Pandemic Network
Our investments help children's hospitals and their communities be ready to care for children during disasters and public health emergencies.

Our Work in this Area
Through Fiscal Year (FY) 2021 cooperative agreement funding, we are establishing a network of children's hospitals located in geographically diverse areas of the country. This network and its pediatric experts will support the nation to better care for the unique needs of children in emergencies. This work will enhance our health care system to:

- Strengthen partnerships in their communities and in existing emergency preparedness systems
- Improve and expand pediatric readiness of the emergency care system, inpatient settings, and out-of-hospital care settings
- Adopt best practices, policies, and research-informed pediatric care

These children's hospitals will serve as hubs in their communities and regions to improve the overall management and care for children during emergencies.

Network Investments
Right now, the network is comprised of two cooperative agreements, which support a network of 10 Children's hospitals:

- University Hospital Cleveland Medical Center's Rainbow Babies, Cleveland, OH
- University of California San Francisco-Benioff Children's Hospital, San Francisco, CA
- University of Louisville School of Medicine-Norton Children's Hospital, Louisville, KY
- University of Utah, Primary Children's, Salt Lake City, UT
- Saint Louis University-Cardinal Glennon Children's Hospital, St. Louis, MO
- Children's National Medical Center, Washington, DC
- Lurie Children's Hospital (LCH) of Chicago, IL
- Seattle Children's Hospital (SCH), Seattle, WA
- University of Alabama at Birmingham (UAB)- Children's of Alabama, AL
- Children's Mercy Hospital, Kansas City, MO

Promoting Our Strategic Goals
This network will promote our strategic goals through enabling:

- **Access:** Increasing the proportion of children's hospitals working in partnership with all levels of emergency preparedness systems
- **Equity:** Advancing health equity in all phases of planning, response, and recovery; making sure hospitals and communities respond effectively during a global health threat to historically under-resourced children and their families
- **Capacity:** Making sure the health workforce and the systems of care are equipped, coordinated, and comprehensive in their response
- **Impact:** Reducing negative health consequences, such as severe illness and death, and promoting the highest level of well-being for children

II. Important Dates

- **RFA Release: December 11, 2023**
- **Applications Due: April 10, 2024**
- **Notification of Awards: May 15, 2024**
- **Award start date: June 1, 2024**

III. Overview

The overall goal of the PPN Mentored Disaster Research Career Development Award program is to assist in the development of a diverse pool of highly trained scientists who will address the Nation's health services, behavioral and clinical research needs in disaster science research as applied to children.

The objective of the PPN Mentored Disaster Research Career Development Award program is to provide salary and research support for a sustained period of "protected time" (2-3 years) to prepare a future cadre of well-trained scientists conducting Disaster Science Research in Pediatrics.

The specific objective of the PDRCD program is to encourage clinical and health services research-oriented physicians and PhDs to develop research skills and gain experience in advanced methods and experimental approaches needed to become independent investigators conducting disaster science research.

It is anticipated that up to 4 awards will be given out. Each award will be funded at $125,000 direct cost per year. **No indirect costs are allowed.**

It is expected that the scholar will:

- **Devote at least 50% of his/her full-time professional effort to the PDRCD program** for the training and clinical research activities. This is based on the entire amount of time worked in a typical week. The remaining 50% effort can be divided among other clinical, administrative, and teaching responsibilities, ideally related to the research focus. Sources of support for the 50% effort include PPN funds of up to $100,000 per year. Any difference between 50% salary support and the $100,000 provided in the award will be covered by the home institution. The PPN will provide an additional $25,000 per year for program related educational and research expenses.
- **Obtain additional research training** through participation in coursework, workshops, and/or individualized programs of study. It is anticipated that all scholars will participate in the one year PPN sponsored Disaster Science Curriculum program.
- **Engage in human-oriented research** relevant to the spectrum of translational research.

- **Develop a mentorship team.** The scholar must select a lead mentor who will have the overall responsibility for helping the scholar develop and carry out a research project in Disaster Research. The lead mentor will provide guidance to assure that the scholar's project is moving satisfactorily on the path to publications, presentations, and grant applications. The lead mentor will also ensure that 50% of the Scholar's effort is protected from clinical and administrative duties and is fully dedicated to the PDRCD program. A co-mentor or mentors may be selected with backgrounds required to assure multi-disciplinary input to the scholar. The lead mentor must have a demonstrated track record of successfully developing the career of junior colleagues and be actively engaged in research.

IV. Eligibility Requirements

Candidates for the PPN Mentored Disaster Research Career Development Award (PDRCD) must:

- Be a US Citizen or Permanent Resident.
- Possess a terminal degree (MD, PhD, PharmD, DMD, DDS, OD, DNS/PhD in nursing, etc.) and at the time of the award be a junior faculty member (assistant professor, instructor or equivalent), in their first 5 years of appointment.
- Commit 50% of professional effort to the program.
- Not be or have been a principal investigator on an NIH R01 or equivalent PHS or non-PHS peer-reviewed research grant that has over $100,000 in direct costs per year. Those who have been PI on an R02 or R21 are eligible. PDRCD applicants may not have any other career development award (K08, K01, K23) at the time of review.
- Develop a multidisciplinary education, training and research plan that includes participation in the PPN Disaster Science Curriculum program.
- Plan to enter a career in Disaster Research
- Have completed training in the Responsible Conduct of Research by the time of grant award.
- Apply for independent research grant support DURING the period of PDRCD support.
- Letter of support from division chief committing at least 50% of protected time if the application is funded
- Applicants who have received a pilot grant from the PPN are eligible to apply for the PDRCD award, and PDRCD scholars are eligible to apply for PPN pilot grant support during their career development award period.

Individuals from groups underrepresented in medicine, women and candidates with disabilities are encouraged to apply.

V. Review Criteria

Overview of Review Process: The review of applications is performed in 2 phases: Scientific Review and Administrative Review. During the first phase, the 12-page applications will be reviewed by 2-3 primary scientific reviewers, who will score the applications. All applications will also be reviewed by members of the Research Domain during a study section meeting. Following this meeting, applicant scores will be tabulated and ranked and PPN PIs and HRSA leadership, serving as a Council, will meet to discuss and determine awardees. Critiques from the first phase of the review will be provided to all applicants after awards are announced.

PDRCD Scientific Review will be consistent with NIH review system and include an assessment of the:

- Candidate
- Career Development Plan/Career Goals & Objectives
- Research Plan
- Mentor, Co-Mentor(s), Consultant(s), Collaborator(s)
- Department/Division Chief's Commitment to the Candidate
- Institutional Environment and core support

Additional Review Criteria include the following:

- Protection of Human Subjects from Research Risk (if applicable)
- Care and Use of Vertebrate Animals in Research (if applicable)
- Biohazards (if applicable)

The reviewers will use the NIH 9-point rating system for the impact priority score of 1 (exceptional) to 9 (poor).

1. Assigned reviewers will provide ratings for each review criteria described above using the 9- point scale.
    - 1 to 3 = high impact
    - 4 to 6 = moderate impact
    - 7 to 9 = low impact
2. An overall score will be assigned to each application in the range of 1-9. Individual reviewer scores will be averaged to determine the final impact score.

VI. Content and Format of Application Submission

The PDRCD application must be submitted in single- spaced text, 0.5-inch margins, no smaller than 11 point with applicant's name in the upper right corner of each page. Required elements are listed in the table below. **The complete application must be uploaded as a single PDF file and submitted electronically through the RedCap link:**

https://cri-datacap.org/surveys/?s=L3JJN9WMLRPNR4J7

R&R Senior/Key Person Profile	Biosketches for all key personnel–including, scholar, lead and co-mentors–using the current NIH template (5-page limit each). http://grants.nih.gov/grants/forms/biosketch.htm
Budget Justification and Budget	Use the Budget Justification to provide a detailed description and justification for specific items within the Research Development Support costs (e.g., all equipment, supplies, and other personnel that will be used to help achieve the career development and research objectives of this award). PHS389 budget form must be included (see Section IX below).
Candidate Section (3-page limit)	Organize your attachment into three sections, following the headings and specified order below, and discuss each of the points listed below. Start each section with the appropriate section heading – Candidate's Background, Career Goals and Objectives, and Candidate's Plan for Career Development/Training Activities During Award Period. Also include any additional information requested in the FOA. **Candidate's Background:** • Describe your past scientific history, indicating how the award fits into past and future research career development. If there are consistent themes or issues that have guided previous work, these should be made clear. Alternatively, if your work has changed direction, indicate the reasons for the change. **Career Goals and Objectives:** • Describe your short-term and long-term career goals. • Justify the need for the award by describing how the career development award will enable you to develop and/or expand your research career. • You are encouraged to include a timeline, including plans to apply for subsequent grant support. **Candidate's Plan for Career Development or Training Activities During Award Period:** • Describe the new or enhanced research skills and knowledge you will acquire as a result of the proposed award. • Describe any structured activities that are part of the developmental plan, such as coursework or workshops that will help you learn new techniques or develop needed professional skills. • For each activity, other than research, explain how it relates to the proposed research and to the career development plan. Indicate the percentage of time to be dedicated to each activity by year, expressed in person-months.

Research Plan Section **(Specific Aims: 1- page limit; Research Strategy: 9-page limit)**	The Research Plan is a major part of the overall career development goal. It is important to relate the proposed research to the candidate's scientific career goals. Describe how the research, coupled with other developmental activities, will provide the experience, knowledge, and skills necessary to achieve the objectives of the career development plan. Also describe how the research and other developmental activities will enable the candidate to launch and conduct an independent research career. The Research Plan is expected to be tailored to the experience level of the candidate and to allow him/her to develop the skills needed for further career advancement. Reviewers will evaluate the plan accordingly. The plan should be achievable within the requested time period. Pilot or preliminary studies and routine data gathering are generally not appropriate as the sole part(s) of a Research Plan. **Specific Aims (1-page limit):** • 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 have on the Disaster Science research field. • List succinctly the specific objectives of the research proposed (e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop new technology). **Research Strategy (9-page limit):** Organize the Research Strategy in the specified order and use the instructions provided below. Start each section with the appropriate heading – Significance, Innovation, Approach: **Significance** • Explain the importance of the problem or critical barrier to progress that the proposed project addresses. • Describe the scientific premise for the proposed project, including consideration of the strengths and weaknesses of published research or preliminary data crucial to the support of your application. • Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields. • Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved. • Describe how the research may address health inequities and involve community engagement Continued >>>

Research Plan Section (continued)	**Innovation** • Explain how the application challenges current research or clinical practice paradigms. • Describe any novel theoretical concepts, approaches or methodologies, instrumentation or interventions to be developed or used, and any advantage over existing methodologies, instrumentation, or interventions. **Approach** • Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Describe the experimental design and methods proposed and how they will achieve robust and unbiased results. Include how the data will be collected, analyzed, and interpreted, as well as any resource sharing plans as appropriate. • For trials that randomize groups or deliver interventions to groups, describe how your methods for analysis and sample size are appropriate for your plans for participant assignment and intervention delivery. These methods can include a group- or cluster-randomized trial or an individually randomized group-treatment trial. Applicants are encouraged to consult with the PPN Analytics and/or Evaluation Domains in developing this section. • Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims. • If the project is in the early stages of development, describe any strategy to establish feasibility, and address the management of any high-risk aspects of the proposed work. • Explain how relevant biological variables, such as sex, are factored into research designs and analyses for studies in vertebrate animals and humans. If you are proposing to gain clinical trial research experience (i.e., you will not be leading an independent clinical trial), briefly describe your role on the clinical trial.

Training in the Responsible Conduct of Research **(1-page limit)**	Applications should describe a plan to acquire instruction in the responsible conduct of research (RCR). Attach a description of plans for obtaining or providing instruction in RCR. This section should document prior instruction or participation in RCR training during the applicant's current career stage (including the date instruction was last completed). This section should also propose plans to receive instruction to meet the frequency requirement of RCR training. The plan must address the five required instructional components: 1. Format: Describe the required format of instruction, i.e., face-to-face lectures, coursework, and/or real-time discussion groups (a plan with only on-line instruction is not acceptable). 2. Subject Matter: Describe the breadth of subject matter (e.g., conflict of interest, authorship, data management, human subjects and animal use, laboratory safety, research misconduct, research ethics). 3. Faculty Participation: Describe the role of the mentor(s) and other faculty involvement in the instruction. 4. Duration of Instruction: Describe the number of contact hours of instruction, taking into consideration the duration of the program. 5. Frequency of Instruction: Instruction must occur during each career stage and at least once every four years. Document any prior instruction during the applicant's current career stage, including the inclusive dates instruction was last completed. The plan may include career stage-appropriate individualized instruction or independent scholarly activities. Instruction and activities should enhance the applicant's understanding of ethical issues related to their specific research activities and the societal impact of that research. The role of the mentor in RCR instruction must be described.

Mentor, Co-Mentor, Consultant, Collaborators Section **(6-page limit total)**	Plans and Statements of Mentor and Co-Mentor(s): The mentor and co-mentor(s) (if applicable) must each document their role and willingness to participate in the project and explain how they will contribute to the development of the candidate's research career. Each statement should include all of the following: 1. The plan for the candidate's training and research career development. Include information not only about research, but also about other developmental activities, such as seminars, scientific meetings, training in RCR, and presentations. Discuss expectations for publications over the entire period of the proposed project. Define what aspects of the proposed research project the candidate will be allowed to continue to pursue as part of his/her independent research program. 2. The source of any additional anticipated support for the candidate's research project for each year of the award period. 3. The nature and extent of supervision and mentoring of the candidate, and commitment to the candidate's development that will occur during the award period. 4. The candidate's anticipated teaching load for the award period (number and types of courses or seminars), clinical responsibilities, committee and administrative assignments, and the portion of time available for research. Address any plan to connect these activities to the career development award. 5. A plan for transitioning the candidate from the mentored stage of his/her career to the independent investigator stage by the end of the project period of the award. Describe the mentor's (and co-mentor's) previous experience as a mentor, including type of mentoring (e.g., graduate students, career development awardees, postdoctoral fellows), number of persons mentored, and career outcomes. **Note for co-mentor statements:** Co-mentors must also address the nature of their role in the career development plan and how the responsibility for the candidate's development is shared with the mentor. Describe respective areas of expertise and how they will be combined to enhance the candidate's development. Also describe the nature of any resources that will be committed to this career development award.
Letters of Support from Collaborators, and Consultants **(6-page limit total)**	Letters of support from collaborators, contributors, and consultants will be required for any such person who will contribute to the scientific development or execution of the applicant's proposed project. Letters are not required for personnel (such as research assistants) not contributing in a substantive, measurable way to the scientific development or execution of the project.

Environment and Institutional Commitment to Candidate Section **(2-page limit)**	Description of Environment and Institutional Commitment to Candidate's Research Career Development: The Department Chair or Division Chief should provide a document on institutional letterhead that describes its commitment to the candidate and the candidate's career development, independent of the receipt of the award. It is also essential to document the institution's commitment to the retention, development, and advancement of the candidate during the period of the award. The "Institutional Commitment to Candidate's Research Career Development" attachment should generally document the institution's agreement to provide adequate time (explicitly state at least 50% effort), support, equipment, facilities, and resources to the candidate for research and career development activities. See the list below for specific items to include in the document. In the document describing its institutional commitment, the applicant organization must: 1. Agree to release the candidate from other duties and activities so that the candidate can devote the required percentage of time for development of a research career. 2. Describe actions that will be taken to ensure that the candidate can devote the required time to research career development (e.g., reduction of the candidate's teaching load, committee and administrative assignments, and clinical or other professional activities). If the candidate's clinical or teaching responsibilities will be reduced, describe how this will be accommodated (e.g., hiring additional staff, reassigning staff). 3. Describe the candidate's academic appointment, bearing in mind that the appointment must be full-time, and that the appointment (including all rights and privileges pertaining to full faculty status if in an academic setting) and the continuation of salary should not be contingent upon the receipt of this award. 4. Describe the proportion of time currently available for the candidate's research and what the candidate's institutional responsibilities will be if an award is made. 5. Describe how the institution will provide the candidate with appropriate office and research space, equipment, and other resources (including access to clinical and/or other research populations) to carry out the proposed Research Plan. 6. Describe how the institution will be supportive of any proposed mentor(s) and/or other staff consistent with the career development plan. 7. **Provide a statement that any difference between 50% salary support and the $100,000 provided in the award would be covered by the home institution.**
Other Project Information Sections	**Bibliography & References Cited** **Facilities & Other Resources:** Describe how the scientific environment in which the research will be done contributes to the probability of success (e.g., institutional support, physical resources, and intellectual rapport). In describing the scientific environment in which the work will be done, discuss ways in which the proposed studies will benefit from unique features of the scientific environment or from unique subject populations or how studies will employ useful collaborative arrangements. If there are multiple performance sites, describe the resources available at each site.

Human Subjects and Clinical Trails Information	It is anticipated that many Disaster Research Projects will be considered exempt from an IRB perspective. However, each project should be reviewed by the institutional IRB to determine this. If not exempt, follow the below procedure. This must be completed by the time of grant award. Protection of Human Subjects attachment that is commensurate with the risks of the study, its size, and its complexity should be provided. Organize your attachment into four sections, following the headings and specified order below, and discuss each of the points listed below. Start each section with the appropriate section heading – Risks to Human Subjects, Adequacy of Protection Against Risks, Potential Benefits of the Proposed Research to Research Participants and Others, and Importance of the Knowledge to be Gained. **1. Risks to Human Subjects** **a. Human Subjects Involvement, Characteristics, and Design** • Briefly describe the overall study design. • Describe the subject population(s) to be included in the study; the procedures for assignment to a study group, if relevant; and the anticipated numbers of subjects for each study group. • List any collaborating sites where human subjects research will be performed, and describe the role of those sites and collaborating investigators in performing the proposed research. **b. Study Procedures, Materials, and Potential Risks** • Describe all planned research procedures (interventions and interactions) involving study subjects; how research material, including biospecimens, data, and/or records, will be obtained; and whether any private identifiable information will be collected in the proposed research project. • For studies that will include the use of previously collected biospecimens, data or records, describe the source of these materials, whether these can be linked with living individuals, and who will be able to link the materials. Describe all the potential risks to subjects associated with each study intervention, procedure or interaction, including physical, psychological, social, cultural, financial, and legal risks; risks to privacy and/or confidentiality; or other risks. Discuss the risk level and the likely impact to subjects. • Where appropriate, describe alternative treatments and procedures, including their risks and potential benefits. When alternative treatments or procedures are possible, make the rationale for the proposed approach clear. **2. Adequacy of Protection Against Risks** **a. Informed Consent and Assent** Describe the process for obtaining informed consent. Include a description of the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. When appropriate, describe how potential adult subjects' capacity to consent will be determined and the plans for obtaining consent from a legally authorized representative for adult subjects not able to consent. Continued >>>

Human Subjects and Clinical Trails Information (continued)	For research involving children: If the proposed studies will include children, describe the process for meeting HHS regulatory requirements for parental permission and child assent (45 CFR 46.408). See the HHS page on Research with Children FAQs and the NIH page on Requirements for Child Assent and Parent/ Guardian Permission. If a waiver of some or all of the elements of informed consent will be sought, provide justification for the waiver. Do not submit informed consent document(s) with your application unless you are requested to do so. **b. Protections Against Risk** • Describe planned strategies for protecting against or minimizing all potential risks identified, including strategies to manage and protect the privacy of participants and confidentiality of research data. • Where appropriate, discuss plans for ensuring necessary medical or professional intervention in the event of adverse effects on participants. • Describe plans for handling incidental findings, such as those from research imaging, screening tests, or paternity tests. **c. Vulnerable Subjects, if relevant to your study** • Explain the rationale for the involvement of special vulnerable populations such as fetuses, neonates, pregnant women, children, prisoners, institutionalized individuals, or others who may be considered vulnerable populations. 'Prisoners' includes all subjects involuntarily incarcerated (e.g., in detention centers). • Pregnant Women, Fetuses, and Neonates or Children: If the study involves vulnerable subjects subject to additional protections under Subparts B and D (i.e., pregnant women, fetuses, and neonates or children), provide a clear description of the risk level and additional protections necessary to meet the HHS regulatory requirements. Refer to HHS regulations and OHRP guidance: HHS Subpart B - Additional Protections for Pregnant Women, Fetuses, and Neonates; HHS Subpart D - Additional Protections for Children; OHRP Guidance on Subpart D Special Protections for Children as Research Subjects; and the HHS 407 Review Process. • Prisoners: If the study involves vulnerable subjects subject to additional protections under Subpart C (i.e., prisoners), describe how proposed research meets the additional regulatory requirements, protections, and plans to obtain OHRP certification for the involvement of prisoners in research. Refer to HHS regulations and OHRP guidance: HHS Subpart C - Additional Protections Pertaining to Prisoners as Subjects; and OHRP Subpart C Guidance on Involvement of Prisoners in Research

Human Subjects and Clinical Trails Information (continued)	**3. Potential Benefits of the Proposed Research to Research Participants and Others** • Discuss the potential benefits of the research to participants and others. • Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to research participants and others. • **Note: Financial compensation of subjects should not be presented as a benefit of participation in research.** **4. Importance of the Knowledge to be Gained** • Discuss the importance of the knowledge to be gained as a result of the proposed research. • Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that reasonably may be expected to result.

VII. Reporting and Evaluation

Scholars and their mentors will meet on a regular basis, agree on productivity goals, discuss the scholar's progress and document these at least quarterly using the Individual Academic Career Development Plan or an equivalent, validated tool. In addition, scholars will be required to submit quarterly progress reports. This will be a proactive process designed to identify and overcome any barriers to success and promote accelerated career development through networking. In addition, scholars will be asked to provide advice and feedback regarding the success of this program and methods for improving it. Documentation from both scholars and their mentors will be submitted at regular intervals.

The PDRCD award allows for two years of guaranteed support. A third year of support may be requested during the 2nd year of funding and determination of funding will be based on the scholar's productivity and finances of the PPN.

VIII. Key CDA Contacts

- Mark Batshaw, MD (mbatshaw@childrensnational.org) – Project Lead
- Rachel Stanley, MD (rachel.stanley@nationwidechildrens.org) – Co-Lead

IX. Useful Links

- Biosketch Template: http://grants.nih.gov/grants/forms/biosketch.htm
- PHS 398 Form Page 4 (Budget Template): http://grants.nih.gov/grants/funding/phs398/phs398.html

pedspandemicnetwork.org

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