Maternal and Pediatric Precision In Therapeutics (MPRINT) Hub
Data and Modeling Knowledge & Research Coordination Center (KRCC)
P30 Opportunity Fund Awards

ELECTRONIC RECEIPT DATE
Application Submission: November 22, 2021

Please note that you will be submitting through the Indiana CTSI's grants management software WebCAMP.

The WebCAMP user's guide is available under the funding announcement here:
https://indianactsi.org/translational-research-development/open-funding-opportunities/

Maternal and Pediatric Precision in Therapeutics (MPRINT)
Knowledge & Research Coordination (KRCC) Program

The MPRINT Hub serves as a national resource for expertise in maternal and pediatric therapeutics to conduct and foster therapeutics-focused research in obstetrics, lactation, and pediatrics while enhancing inclusion of people with disabilities. By serving as a national resource, it aggregates, presents, and expands the available knowledge, tools, and expertise in maternal and pediatric therapeutics to the broader research, regulatory science, and drug development communities.

The IU/OSU MPRINT KRCC coordinates and supporst the operations of the entire MPRINT Hub, providing a knowledge base that will aggregate and identify knowledge deficits in the principles of maternal and pediatric therapeutics including pharmacokinetics, pharmacodynamics, genetics, proteomics, and metabolomics that inform drug development and regulatory science.

Applicants are encouraged to utilize MPRINT Hub cores:

1. **Knowledgebase & Portal Core** is developing a knowledgebase of data and resources relating to maternal and pediatric therapeutics, including pharmacokinetics, pharmacodynamics, pharmacogenetics, pediatric ontogeny and the physiological changes that occur with and around pregnancy and lactation. The Knowledgebase & Portal Core is developing common data elements and ontologies for annotating these data; develop text classification algorithms to identify relevant published literature; and integrate various data sources into an accessible web portal. Contact: Lang Li, PhD Lang.Li@osumc.edu
2. **Pharmacometrics & Clinical Trial Design Core** provides expertise in pharmacokinetic (PK) and pharmacodynamic (PD) modeling, biostatistics, and clinical trial design. Investigators bring expertise in clinical pharmacology study and pharmacometric modeling approaches including population pharmacokinetics (PK), physiologically based (or mechanistic) PK/PD, machine learning, pharmacogenomics (PG), and Bayesian methods and adaptive trial design. Contact: Sara Quinney, PharmD, PhD squinney@iu.edu
3. **Real-world Evidence Core** brings together experts and resources from the Regenstrief Institute at Indiana University, the Indiana Health Information Exchange (IHIE), and Information Technology groups across our partner healthcare systems, Nationwide Children's Hospital and Ohio State University. They can support a variety of studies through leveraging and building upon expertise and robust real-world data resources. Contact: Eneida Mendonca emendonc@iu.edu
4. **Phenotyping Core** at Vanderbilt University Medical Center provides expertise in using electronic health records, including Vanderbilt's BioVU biobank resource, and techniques like clinical terminologies, natural language processing, and machine learning to better understand response to medications. Contact: Wei-Qi Wei MD, PhD wei-qi.wei@vumc.org and Henry Ong, PhD henry.ong@vumc.org
5. **Milk Analtyics Core** has expertise in collecting and processing human milk samples and performing a variety of human milk assays including macronutrients, oligosaccharides, microbiomes, and other multiplex assays. Contact: Lars Bode lbode@ucsd.edu
6. **Pharmacometric and Analtyical Chemistry Core** is housed within the UCSD Pediatric Pharmacology Laboratory and performs quantitative drug and metablolte assays in small sample volumes and heterogenous matrices, including plasma, tissue, and breast milk. Contact: Jeremiah Momper jmomper@health.ucsd.edu

Awards: We anticipate funding a combination clinical fellow / postdoctoral fellow awards up to $25,000 and faculty awards up to $150,000 (total costs) for a total award amount in the range of $500,000. Awards will be for a 12-month period.

Eligibility: Proposals are accepted from clinical or basic science investigators, deemed eligible to serve as a PI for external funding at their institution, and who are affiliated with any MPRINT institution, or with any other

academic institution. Cross collaborations between departments and institutions is highly encouraged and KRCC Core usage is encouraged but not required. *Faculty that hold the title of visiting rank are not eligible*

APPLICATION PROCESS AND SUBMISSION

Full applications are due on November 22, 2021. Submissions are via the 'Start a submission' link found here MPRINT Link

1. **Face Page**
   The face page specifies the title of the proposal, principal investigators and his/her affiliation, collaborator(s) and affiliation, where work will be performed, and the total budget. Department / School support must be indicated by completion of all appropriate signatures on the face page(s) FOR EACH PI/CO-PI. As submission will be electronic only, facsimile or electronic signatures are appropriate.

2. **Abstract & Keywords**
   - The abstract should be a brief (500 word maximum) abstract in layman's terms.
   - Provide 5 keywords that describe the research content of your project

3. **Budget**
   Budget page listing total costs. This page may be duplicated and a separate budget page included for each performance site / collaborating institution. Requested grant funding period cannot exceed **12 months**.
   - Projects should have a start date no earlier than **January 1, 2022.**
   - No Faculty salary should be included, but anticipated effort should be stated in budget justification.
   - Supplies and other costs must relate directly to performance of the project.
   - Travel beyond that which is necessary between the institutions / campuses will require justification.
   - Salaries / stipends for technicians, graduate students, postdoctoral fellows are allowed.
   - If utilizing a MPRINT Core, a letter of support, should be included.
   - All costs should be specifically justified and expenditures for each participating partner/institution clearly denoted.

5. **Specific Aims (one page maximum):** Describe the specific aims of the proposal and how the aims relate to advancing maternal and/or pediatric pharmacotherapy and ongoing efforts of the MPRINT HUB.

6. **Research Plan:** The Research Plan narrative **should not exceed 3 pages** and should include Significance, Innovation, and Approach. Proposals from faculty should also state how the proposal will support future research plans and funding.

7. **References Cited** (not included in the Research Plan page limit)

8. **Biosketch:** Biographical sketch (5-page maximum) of the principal investigators and co-investigator/collaborator in the NIH format available at https://grants.nih.gov/grants/forms/biosketch.htm.

9. **Other support for the principal investigator and each co-investigator / collaborator**: Include detail on any overlap that this proposal has with active or pending awards. This information must be provided in NIH format.

10. **Supporting documentation**:
    - Applicants are encouraged to provide a letter of support from a biostatistician and/or bioinformatician.
    - If one of the MPRINT Cores is being used, include a letter of support from the Core Director.

For questions related to budgeting and grant submissions, please contact: Sandra Milescu sanmiles@iu.edu

REVIEW, AWARD SELECTION & FUNDING TIMELINE

Requests for funds will be reviewed by the MPRINT Steering Committee in November and critiqued on the following items:

- The strength of the research
- Likelihood of providing the preliminary data required for an external grant submission
- Impact on the focus areas and ongoing efforts of HUB

POST AWARD REQUIREMENTS & EXPECTATIONS

1. It is expected that data from awards will adhere to open sharing data plans established by the MPRINT Hub, including but not limited to, uploading of relevant data and modeling codes to the MPRINT Hub Portal.
2. Awardees will be expected to present study findings at the MPRINT Hub Annual Scientific Meeting.
3. All awards will be monitored for progress by the MPRINT Hub Steering Committee. Progress monitoring generally includes the following from all project PIs:
    - Annual progress reports due in June that report status of milestone progress along with documentations of external grant submissions/awards, IP, publications, and/or presentations arising from the supported research.
    - Annual follow-up reports upon request for up to 3 years after the project ends, including but not limited to the following data:
        - External grant submissions and awards arising from the supported research
        - Intellectual property arising from the supported research
        - Publications arising from the supported research
        - Additional impacts of the award on your research and the collaboration
4. It is expected that this pilot funding will lead to publication(s) and external funding submission(s), generally reported on the annual progress reports.
5. Grant recipients are required to acknowledge receipt of MPIRNT support in any presentation or publication of work funded this award as follows:

    This [(publication was made possible) (project was supported)] by 1P30HD106451 from the Eunice Kennedy Shriver National Institute of Child Health and Human Development.