

**Maternal and Pediatric Precision In Therapeutics (MPRINT) Hub
Data, Model, Knowledge & Research Coordination Center (DMKRCC)
P30 Opportunity Pool Awards**

ELECTRONIC RECEIPT DATES:

LOI Submission: **April 30, 2023**

Invited Application Submission: **May 31, 2023**

Notification of Award: **No later than July 31, 2023**

Funding period ends: **July 31, 2024**

Maternal and Pediatric Precision in Therapeutics (MPRINT) Data, Model, Knowledge & Research Coordination (DMKRCC) 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 DMKRCC coordinates and supports 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: Shaun Grannis sgrannis@regenstrief.org and Christopher Bartlett Christopher.Bartlett@NationwideChildrens.org
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 Analytics 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 Analytical Chemistry Core** is housed within the UCSD Pediatric Pharmacology Laboratory and performs quantitative drug and metabolite assays in small sample volumes and heterogeneous matrices, including plasma, tissue, and breast milk. Contact: Jeremiah Momper jmomper@health.ucsd.edu

Scope: The Opportunity Pool is designed to *support projects that address emergent needs and leverage novel technologies in maternal and pediatric therapeutics*. Examples of supported activities include, but are not limited to, expansion of existing or development of a new MPRINT Core and generation of new computational or experimental tools to enhance precision therapeutics in maternal and pediatric populations.

Priorities: Priority will be given to projects that address emergent needs, develop new resources, or leverage use of a MPRINT Hub core. Priority will also be given to projects that build collaborations with an MPRINT site or cross-collaboration between departments and institutions is highly encouraged.

Awards: Applicants are encouraged, but not required, to utilize MPRINT Hub cores. Awards will be for a 12-month period. We anticipate funding a combination of clinical fellow / postdoctoral fellow awards up to \$25,000 and faculty awards up to \$150,000 for a total award amount in the range of \$500,000. Proposals are accepted from clinical or basic science investigators, deemed eligible to serve as a PI for external funding at their institution. Cross-collaboration between departments and institutions is highly encouraged. Opportunity Pool Awards are managed through the Indiana University-Ohio State University MPRINT Data, Model, Knowledge, and Research Coordination Center (IU-OSU MPRINT DMKRCC)

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 TIMELINE

- Applicants must submit a 1-page Letter of Intent (LOI) describing the proposed research project to the MPRINT Hub via email to info@mprint.org by **April 30, 2023**.
- The MPRINT Hub DMKRCC will review LOIs for consideration as they are received.
- Eligible applicants will be invited to submit a full application and will receive the link to apply.
- Applicants must submit application/required documents via *the Indiana CTSI's grants management software WebCAMP* by **May 31, 2023**
- Proposals will be reviewed by the MPRINT SC
- Notification of award will occur **no later than July 31, 2023**
- The funding will be **August 1, 2023 through July 31, 2024**

APPLICATION PROCESS AND SUBMISSION

Full applications are due on May 31, 2023.

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 **August 1, 2023**.
- 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.

- If this is a resubmission of a prior MPRINT funding proposal, include a one-page response to the reviewers' comments and include the review documents.

For questions related to budgeting and grant submissions, please email info@mprint.org

REVIEW, AWARD SELECTION & FUNDING TIMELINE

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

- The significance, innovation, and 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 the MPRINT HUB

POST AWARD REQUIREMENTS & EXPECTATIONS

1. Awardees will need to fulfill all JIT requests from the MPRINT DMKRCC grant management office (IRB, IACUC, budget clarification, etc.)
2. Awardees are expected to fulfill the following expectations:
 - a. Provide a 1-paragraph summary of the project to be included on the MPRINT Hub website.
 - b. Participate in and present your work at the MPRINT Annual Meeting and/or other MPRINT Webinars, as requested.
 - c. Report co-authored, peer-reviewed, publications and presentations based on findings from your project to the MPRINT DMKRCC. These are generally reported on the annual progress reports which occur for 5 (five) years following completion of your project.
 - d. Notify the MPRINT DMKRCC in writing of major changes in the project, including changes in key personnel or >25% changes in budgets.
3. 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.
4. All awards will be monitored for progress by the MPRINT Hub Steering Committee. Progress monitoring generally includes the following from all project PIs:
 - a. Annual progress reports due in May that report status of milestone progress along with documentations of external grant submissions/awards, IP, publications, and/or presentations arising from the supported research.
 - b. Annual follow-up reports upon request for up to 3 years after the project ends, including but not limited to the following data:
 - i. External grant submissions and awards arising from the supported research
 - ii. Intellectual property arising from the supported research
 - iii. Publications arising from the supported research
 - iv. Additional impacts of the award on your research and the collaboration
5. Complete annual progress reports while the project is still active and then annually for five years thereafter. This reporting schedule will allow the MPRINT Hub to report results from this funding over the lifetime of its award. Progress report requests will be sent out in April.

Note that the progress report will be sent to ONLY 1 investigator (designated as the contact PI) and that individual will be responsible for collecting data from all collaborators for the project and submitting the required progress reports. In addition, if the report is not submitted on time the account may be frozen until the progress report is received.
6. It is expected that this pilot funding will lead to publication(s) and external funding submission(s), generally reported on the annual progress reports.
7. Awardees will assure compliance with the MPRINT Hub Data Use and Sharing Agreements and NIH Public Access Policy and Data Sharing requirements. Data, models, and other resources generated via the MPRINT Hub will be made available through the MPRINT Hub Knowledgebase and Portal website. Additionally, data will be submitted to other public repositories, such as the NICHD Data and

Specimen Hub, as appropriate. In accordance with NIH requirements, all publications must be submitted to National Library of Medicine Pubmed Central in an electronic version of their final, peer-reviewed manuscripts upon acceptance for publication to be made publicly available no later than 12 months after the official date of publication. Information regarding the NIH requirement and compliance can be found at <https://publicaccess.nih.gov/policy.htm>.

8. Postdoctoral/Fellowship awardees are expected to participate in career development and educational activities offered through the MPRINT Hub. This includes, but is not limited to, attending webinars, attending MPRINT Educational Workshops, and seeking input and support from appropriate MPRINT Cores (e.g. Pharmacometrics and Clinical Trial Design Core, Real-World Evidence Core, Phenotyping Core, Milk Analytics Core).
9. Cite the MPRINT DMKRCC grant for all publications and presentations:
"This [(publication was made possible) (project was supported), or (project was funded)], in part, with support from The Indiana University-Ohio State University Maternal and Pediatric Precision in Therapeutics Data, Model, Knowledge, and Research Coordination Center (IU-OSU MPRINT DMKRCC), in part by Grant Number P30HD106451 from the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) Obstetrics and Pediatric Pharmacology and Therapeutics Branch (OPPTB). The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health."