

# Maternal and Pediatric Precision in Therapeutics (MPRINT) Hub

## Frequently Asked Questions

*Last revised: October 20, 2020*

The following intends to address general questions associated with application submission and award management that may arise in relation to NICHD's Maternal and Pediatric Precision in Therapeutics (MPRINT) Hub (<https://www.nichd.nih.gov/about/org/der/branches/opptb/mprint>). The MPRINT Knowledge and Research Coordination Center (KRCC; [RFA-HD-21-025](#)) will interface with the MPRINT Centers of Excellence in Therapeutics (CETs; [RFA-HD-21-026](#)), to serve as a national resource for knowledge and expertise in maternal and pediatric pharmacology and as a research center to close deficits in knowledge and technical expertise.

To be notified of revisions to the frequently asked questions (FAQs) and other updates, please sign up at <https://www.surveymonkey.com/r/MPRINT>

### 1. General Questions

**Q:** How will the components of the MPRINT Hub function?

**A:** The MPRINT KRCC P30 is the administrative structure and technical and scientific infrastructure needed to support MPRINT Hub activities, responsible for knowledge aggregation and dissemination. The MPRINT CET P50 will address key knowledge deficits in maternal and pediatric pharmacology and therapeutics via novel clinical, translational, basic, and/or data sciences research.

**Q:** What is the scope of the awards - MPRINT KRCC P30 and/or MPRINT CET P50? Is there specific disease state or therapeutic area of interest?

**A:** For the purpose of this Funding Opportunity Announcement (FOA), there are no specific disease states or therapeutic areas of interest. However, therapeutic treatment of obstetric and breastfeeding conditions as well as therapeutic treatment of pediatric disease, particularly where there are unique pediatric conditions or pharmacodynamic differences from adult disease, could be a focus of proposed programs.

Also refer to the section of the Requests for Applications (RFAs), entitled "**Applications that are not responsive to this funding announcement**", for more information about what is not within scope.

**Q:** Should I contact the Program Official before applying for one of the RFAs?

**A:** While not mandatory, engaging your Program Official early in the process will help you determine if you are eligible and could make the difference between proposing something that would not be responsive for this FOA and something else that would be within scope. *It is strongly recommended you contact a program officer before beginning an application.*

**Q:** Will the informational webinar (scheduled for 10/8/20) be the only opportunity to ask questions?

**A: No.** Interested applicants may email their questions or set-up time with the respective the Program Officer to discuss applications as soon as they want. Interested applicants should not wait for the informational webinar but may ask questions during the informational webinar.

**Q:** Is the MPRINT Hub intended to replace NICHD-supported clinical trial infrastructure such as The Maternal Fetal Medicine Network, Neonatal Research Network, or the Pediatric Trials Network? How is this MPRINT Hub different from these networks?

**A: No.** The MPRINT Hub will serve 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. It will enhance current and future clinical trial infrastructure as well as other maternal and pediatric pharmacology and therapeutics projects. You may refer to the **NICHD Vision for Multisite Clinical Trials Infrastructure:** <https://www.nichd.nih.gov/about/meetings/2019/110119> for additional information on NICHD clinical trial infrastructure

**Q:** Can applicants apply to both RFAs (MPRINT KRCC P30& MPRINT CET P50)?

**A: Yes.** Applicants can apply to both RFAs, with no overlap on budget and research efforts.

**Q:** Can you clarify the definition of “people with disabilities”/ “those with disabilities” and how I may address this in my project?

**A:** Section 504 of the Rehabilitation Act of 1973 and the Americans with Disabilities Act defines the terms "handicap" or "disability" with respect to an individual to mean a physical or mental impairment that substantially limits one or more of the major life activities of such an individual. Applicants for the MPRINT KRCC P30 should describe, at a minimum, how pharmacometric models will be adapted to account for individuals with disability. Applicants for the MPRINT CET P50 should, at a minimum, not exclude those with disabilities from clinical trials or research.

Also refer to the section of the RFA, entitled “**Research Strategy**”, for more information.

## 2. Questions Specific to MPRINT Hub Organization

**Q:** What will the overall breakdown be for the Hub, in terms Maternal vs Pediatrics focus?

**A:** Final funding decisions of awards will be made a manner to assure that there is approximately equal distribution of study between maternal pharmacology and pediatric pharmacology across the MPRINT Hub. However, each individual award does not need to have a 50:50 balance between maternal and pediatric pharmacology and therapeutics.

It is expected that MPRINT KRCC P30 award will have a strong balance between maternal and pediatric pharmacology and therapeutics.

The MPRINT CET P50 awards do not need to be as balanced. However, to be responsive, MPRINT CET P50 applications must include studies relating to both maternal and pediatric therapeutic science. Individual Research Projects or Support Cores may have either a maternal or pediatric focus or the maternal and pediatric aspects may be woven throughout Cores and Research Projects of the application.

**Q:** Are fetal and neonatal studies considered pediatrics for purposes of determining the breakdown of the maternal vs pediatric composition of the MPRINT Hub and its components?

**A: Yes.** Neonatology would be considered as pediatrics in assessing balance across the MPRINT Hub and responsiveness of applications.

**Q:** How will individual awards be organized and managed within the MPRINT Hub?

**A:** Activities of the MPRINT KRCC and CETs will be undertaken with input from a Steering Committee composed of MPRINT Hub awardees in addition to feedback from the MPRINT Hub's External Program Consultants (EPCs) and the NICHD. The Chair(s) of the SC will be selected by the NICHD from the PDs/PIs of the MPRINT Hub awardees. The MPRINT SC will establish procedures for the function of the Hub, including monthly SC teleconferences and, as necessary, convene working groups of the SC for specific purposes. At least once yearly, the Steering Committee and other key personnel are expected to convene an in-person meeting (or virtual equivalent) to review scientific progress, highlight key Hub activities, and communicate with NICHD staff. The MPRINT Hub will establish strong working relationships with other related efforts, including collaborative projects, and will share scientific approaches and data prior to publication. External Program Consultants (EPCs) will be selected by the NICHD to review the functioning and progress of the Hub and ensure the Hub is operating optimally and efficiently.

**Q:** What are examples of the potential uses of the MPRINT KRCC P30 opportunity pool funds?

**A:** Opportunity funds are used to address emergent needs in support of national research in maternal and pediatric therapeutics. Funds may be awarded to investigators outside of the home institution. Opportunity Pool can support activities such as, but not limited to:

- Expansion of a Core within the MPRINT Hub to handle greater than expected demand from the broader scientific community;
- Establish a new Core function within the MPRINT Hub to address emergent needs in maternal and pediatric therapeutics;
- Generation of new computational or experimental tools that may enhance precision dosing in maternal and pediatric populations.

Applicants should also describe how the MPRINT KRCC will solicit, review, and select internal and external proposals for funding. Opportunity Pool funds will be restricted and projects will require prior approval by NIH prior to initiation.

**Q:** Does the MPRINT KRCC P30 handle the data base and statistical needs of the MPRINT CET P50? Does the MPRINT KRCC P30 provide the DSMB and regulatory oversight that may be required by the P50 studies?

**A: No.** All MPRINT CET P50 applications/projects are expected to be self-contained, independently providing resources needed to fully complete all proposed P50 projects. The MPRINT KRCC P30 will only provide network-wide logistical coordination.

**Q:** Will the KRCC serve as a data and specimen coordinating center for the P50 studies?

**A: No.** The MPRINT KRCC will not serve as a specific a data and specimen coordinating center for the P50s, however the Knowledge Base and Portal of the MPRINT KRCC will serve as the primary database, integrator, and analytical platform for publicly available data and knowledge, including data produced by other components of the MPRINT Hub such as the CETs.

**Q:** Is it expected that the MPRINT CET P50 components fully cover fetal life through adolescence to fulfill the pediatric requirement?

**A: No.** MPRINT CET P50 may focus on a specific stage of human growth and development, from fetal life through adolescence. For example, an MPRINT CET P50 application may focus on neonatology or adolescence.

*Disclaimer:* The MPRINT KRCC P30 does require that application components address the full spectrum of pediatric development.

### 3. Grant Application Format and Content

**Q:** As the MPRINT Hub will require an inter-disciplinary, team science approach, are there any resources on how to manage such collaborations?

**A:** The following link serves as a valuable resource for scientists participating in or leading a research team: <https://www.cancer.gov/about-nci/organization/crs/research-initiatives/team-science-field-guide/collaboration-team-science-guide.pdf>

**Q:** How thorough should Research Project and Core details be described in the application?

**A:** Research Project and Core descriptions should be as descriptive as needed to fully explain their role in the overall proposal and how it will interact with other components of the MPRINT Hub in establishing the MPRINT Hub as a central resource for national activities in maternal and pediatric therapeutics research. Articulating the strategies to be used to address the specific tasks detailed in the objectives and scope section of the RFA that addresses the broad goals of the MPRINT program is an important element of the application. Applicants should be sure to address all elements under the Research Strategy section of each component.

**Q:** Is there a limitation on the type of Optional Core that can be proposed for the MPRINT KRCC P30?

**A: No.** Applicants must clearly state how the Core will contribute to the overarching goals of the MPRINT KRCC as well as outline interactions of the core with each of the other cores of the Center. Optional Cores are not mandatory. There is a maximum of **one** proposed Optional Core for a MPRINT KRCC P30.

**Q:** Is there a limitation on the type of Support Cores that can be proposed for the MPRINT CET P50?

**A: No.** Applicants must clearly state how the Supports Core will contribute to the overarching goals of the MPRINT CET as well as outline interactions of the Support Core with Research Projects and other Cores. There must be at least one and maximum of **two** proposed Support Cores (P50).

**Q:** What specific disease state or therapeutic area of interest should applications focus on?

**A: No.** There are no specific disease states or therapeutics areas that need to be focused on. Proposed Research Projects and Cores should promote the NICHD's [2020-2024 Strategic Plan](#), addressing current/future problems and critical barriers to advancing drug development in maternal and pediatric therapeutics and improving scientific knowledge, technical capability, and ultimately enable maternal and pediatric drug development. For proposals addressing barriers in

pediatrics, explain how this Research Project relates to the priorities of the Best Pharmaceuticals for Children Act (<https://www.nichd.nih.gov/sites/default/files/inline-files/2020PriorityListFeb20.pdf>).

**Q:** Does the MPRINT Hub prioritize traditional small molecules therapeutics or can MPRINT CET P50 projects include other therapeutics (e.g., proteins, exosomes)?

**A: No.** The MPRINT Hub is open to all therapeutics.

**Q:** For the MPRINT CET P50s, what is example of an acceptable clinical pharmacology project that involves a specific therapeutic that is not focused primarily on changing clinical practice

**A: No.** Projects focusing on specific therapeutics or drug studies designed to change clinical practice or labeling are **not** responsive. Clinical projects that use an existing therapeutic to provide resources and/or generate novel tools and approaches to advance novel therapeutics to the broader scientific community would be acceptable.

*Example:* Conducting clinical trials of Drug X solely to identify dose ranges for children would not be responsive. If Drug X is used as a probe in different age groups/stages of development to gain information related to age-specific changes in drug metabolizing enzymes, transporters, etc. in these different age groups and this information can also be used to identify appropriate dosing for those age ranges, that may be responsive.

For determination of scope and/or responsiveness of individual projects, contact the respective Program Officer.

**Q.** May applications propose Phase I/II studies as an example of how to advance novel therapeutics?

**A.** It depends. If the purpose of Phase I/II studies is solely to advance a novel therapeutic, the application would likely not be responsive. If the purpose of the Phase I/II studies are to provide validation of new tools that can be used in additional Phase I/II studies, the application may be responsive.

For determination of scope and/or responsiveness of individual projects, contact the respective Program Officer.

**Q:** What are the expectations for the innovation component of the application and how will innovation be critiqued?

**A:** Responsive applications will be those that describe how proposed resources will serve to shift current maternal and pediatric clinical research and/or drug development paradigms through use of novel tools, approaches, methodologies, and/or modeling. Refer to “**Section IV. Application and Submission Information**” for specific instructions for innovation under Research Strategy” and to “**Section V. Application Review**” for specific review criteria related to Innovation for each component of either RFA.

**Q:** Can you provide more information of the use of DASH?

**A:** For human data, the NICHD encourages the use of the Data and Specimen Hub (DASH), a centralized resource for researchers to store and access de-identified data from studies funded by NICHD. DASH serves as a mechanism for NICHD-funded extramural and intramural investigators to share research data from studies in accordance with NIH Data Sharing Policies. DASH will store and make available to other investigators the biospecimen catalog for studies that have associated research data in NICHD DASH.

For more information, refer to <https://dash.nichd.nih.gov/>.

**Q:** Should the MPRINT CET P50 address a Data Sharing plan for the MPRINT KRCC P50?

**A: No.** This is an error. It currently reads in the FOA: “All applications, regardless of the amount of direct costs requested for any one year, must address a Data Sharing Plan for the full **KRCC** in the Overall component of the application.”

It should read in the FOA: “All applications, regardless of the amount of direct costs requested for any one year, must address a Data Sharing Plan for the full **CET** in the Overall component of the application.”

## 4. Grant Submission and Review Process

**Q:** How can I submit my grant?

**A:** Organizations must submit applications to [Grants.gov](https://grants.gov) (the online portal to find and apply for grants across all Federal agencies) using the NIH ASSIST system or via an institutional system-to-system. For assistance with your electronic application or for more information on the electronic submission process, visit [How to Apply – Application Guide](#).

Please refer to “**Section IV. Application and Submission Information**” of the RFA.

**Q:** Where will my grant application be reviewed?

**A:** Applications will be reviewed by one or more Special Emphasis Panels (SEPs) convened by the NICHD’s Scientific Review Branch. Each RFA will have its own SEP.

**Q:** How would each component of the MPRINT KRCC P30 and/or MPRINT CET P50 be evaluated?

**A:** As applicable, reviewers will evaluate the review criteria items while determining scientific and technical merit for the entire application, and in providing an overall score and a score for each applicable Cores. The 5 review criteria (Significance, Investigator(s), Innovation, Approach, Environment) for the overall application will **not** be individually scored. An application does not need to have a strong score in all core components to have a good overall score.

Please refer to “**Section V. Application Review Information**” of the RFAs for complete information.

**Q:** If applications are submitted for both the MPRINT KRCC P30 and MPRINT CET P50 grants, will there be different study sections for each RFA?

**A:** Ultimately the decision on how to manage the review(s) will be up to the scientific review officers (SROs).

Please refer to “**Section IV. Application and Submission Information**” of the RFA.

**Q:** What is NIH's policy regarding the submission of late grant applications?

**A:** Permission is not granted in advance for submission of a late application. Late applications are accepted only in extenuating circumstances. If an application is submitted late, a cover letter explaining the reasons for the delay must be included with the signed, completed application. Late applications are evaluated on an individual basis considering the reasons provided. Contacting the Division of Receipt and Referral in advance will not influence the acceptance of a late application.

#### Examples of Reasons Why Late Applications Might Be Accepted:

- Death of an immediate family member of the PD/PI (or MPI).
- Sudden acute severe illness of the PD/PI (MPI) or immediate family member.
- Temporary or ad hoc service by a PD/PI on an NIH advisory group during **the two months preceding or the two months following** the application due date. Examples of qualifying service include: participation in an NIH study section/special emphasis panel, NIH Board of Scientific Counselors, Program Advisory Committee, or an NIH Advisory Board/Council. Qualifying service does not include participation in NIH activities **other than** those involved in extramural/intramural peer review or NIH Advisory Council/Board service.
- Delays due to weather, [natural disasters, or other emergency situations](#), not to exceed the time the applicant organization is closed.
- For PD/PIs who are eligible for continuous submission ([https://grants.nih.gov/grants/peer/continuous\\_submission.htm](https://grants.nih.gov/grants/peer/continuous_submission.htm)), the late application policy applies to activities not covered under the continuous submission policy (i.e., other than R01, R21, and R34 funding opportunities that use standard due dates).

Please refer to **Notice #NOT-OD-15-039** (dated December 17, 2014) for more information- [NIH Policy on Late Submission of Grant Applications](#).

## 5. Questions Specific to Applications with Multiple PD/PIs or from Multiple Institutions

**Q:** What is the definition of Program Director/Principal Investigator (PD/PI) on a multiple-PD/PI grant?

**A:** The PD/PI is defined the same way regardless of the number named on a particular application or award. The Program Director/Principal Investigator (PD/PI) is defined as the individual(s) judged by the applicant organization to have the appropriate level of authority and responsibility to direct the project or program supported by the grant. The applicant organization may designate multiple individuals as PD/PIs who share the authority and responsibility for leading and directing the project, intellectually and logistically. Each PD/PI is responsible and accountable to the applicant organization, or as appropriate, to a collaborating organization, for the proper conduct of the project or program including the submission of all required reports. The presence of more than one identified PD/PI on an application or award diminishes neither the responsibility nor the accountability of any individual PD/PI.

**Q:** Are multiple PIs allowed for these applications?

**A: Yes.** Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the Program Director(s)/Principal Investigator(s) (PD(s)/PI(s)) is invited to work with his/her organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH support.

For institutions/organizations proposing multiple PDs/PIs, visit the Multiple Program Director/Principal Investigator Policy and submission details in the Senior/Key Person Profile (Expanded) Component of the SF424 (R&R) Application Guide.

**Q:** What happens if one or more PD/PIs are not well qualified for the role according to the stated criteria? Will this affect the score?

**A:** Similar to a single PD/PI application, the qualifications of PD/PIs in the multiple-PD/PI application will be considered during peer review and in establishing priority scores. All listed PD/PIs must meet the qualifications included in the PD/PI

definition and each must have a clearly identified role on the project. As in single PD/PI applications, reviewers will judge the quality of the application as submitted. The inclusion of individuals who do not appear to be qualified as PD/PIs or have ambiguous roles on the project or within the leadership team are likely to be reflected in the score.

**Q:** In what format should multiple institution projects be submitted?

**A:** PD/PIs at different institutions may collaborate on the development of a multiple PD/PI application. However, a single application should be submitted from one institution that identifies all PD/PIs, including those from institutions other than the applicant institution

**Q:** Can I be a PI on more than one application to the same RFA or be on more than one application to both RFAs?

**A:** Applicants are free to apply to the companion RFA and to more than one application of same program.

**Q:** Can an Investigator from a foreign institution serve as a PI on a multi-PI application?

**A:** Non-domestic (non-U.S.) Entities (Foreign Institutions) **are not** eligible to apply. Non-domestic (non-U.S.) components of U.S. Organizations **are not** eligible to apply. Foreign components, as defined in the [NIH Grants Policy Statement](#), **are** allowed.

## 6. Budget Information

**Q:** How many awards will be made for the MPRINT KRCC P30 and at what funding level?

**A:** For the MPRINT KRCC P30, NICHD intends to commit \$3,000,000 total costs (including subcontract indirect (F&A) costs) in Fund Year (FY) 2021 to **fund 1 award**. (\$3M Award is direct costs + F&A costs)

**Q:** How many awards will be made for the MPRINT CET P50 RFA?

**A:** For the MPRINT CET P50, NICHD intends to commit \$2,500,000 total costs (including subcontract F&A) in FY 2021 to **fund 2 awards**. Application budgets are limited to \$850,000 in direct costs per year (excluding subcontract F&A) and need to reflect the actual needs of the proposed project. (\$2.5M Award is direct costs + F&A costs)

**Q:** How do we budget for the Opportunity Pool (P30) or Support Pool (P50)?

**A:** For the opportunity pool (P30), applicants should budget for a total of \$500,000 total costs **per year** under the other expenses within the Logistics Core budget as a separate line in the composite budget. For the support pool (P50), applicants should budget for a total of \$150,000 total costs **per year** under the other expenses within the administrative core budget as a separate line in the composite budget.

More information can be found under “**Budget (Administrative Core)**” of each RFA.

**Q:** How will the opportunity pool (P30) or support pool (P50) managed?

**A:** Plans to solicit, review, select, and award the Opportunity Pool (P30) or Support Pool (P50) funds should be clear, appropriate, and proposed by the applicant. The Logistics Core will oversee use of the Opportunity Pool funds whereas the Support Pool will be overseen by the Administrative Core. Awardee-selected Pool projects require prior approval by NIH prior to initiation.

**Q:** What are F&A costs?

**A:** F&A costs represent the expenses of doing business that are not readily identified with a particular grant, contract, project function or activity, but are necessary for the general operation of the organization and the conduct of activities it performs. Examples include depreciation and use allowances for an organization's building and equipment, operation and maintenance expenses, sponsored projects administration, and departmental administration.

F&A costs are determined by applying your organization's negotiated F&A rate to your direct cost base. Most educational, hospital, or non-profit organizations have negotiated their rates with other Federal (cognizant) agencies such as the Department of Health and Human Services or the Office of Naval Research.