

## Boilerplate Description of Maternal and Child Health Research Institute Services

*Below is a boilerplate description of MCHRI Services at Stanford. This text can be inserted into the resource section of your grant proposals and edited as necessary to meet your needs (Updated 9/23/2020).*

### **Stanford Maternal and Child Health Research Institute – Research Coordinator Services**

The Stanford Maternal and Child Health Research Institute (MCHRI) services are highly integrated with the overall clinical research support infrastructure at Stanford and Spectrum, the Stanford Clinical and Translational Research Center funded by the NIH CTSA. MCHRI offers a child-health-focused, centralized pool of clinical research coordinators, consultative services, study implementation strategies, study budget development, and protocol feasibility assessment. Our clinical research coordinators partners with their PIs to ensure their studies are well supported in compliance to Stanford policies and requirements.

These services are available to all Stanford faculty, clinician educators and trainees participating in clinical and translational research in maternal and child health, enabling the program to support more than 100 studies per year. Services and expertise include:

- Centralized pool of clinical research coordinators
  - ✓ Child-health focused
  - ✓ Institutional knowledge
  - ✓ Structured onboarding / training
  - ✓ Serve as trainers for non-pool research staff
  - ✓ Support Federal and Industry sponsored studies
- Support throughout lifecycle of research study
  - ✓ Study Start-Up
  - ✓ Budget Development
  - ✓ Protocol refinement, implementation strategies
  - ✓ Regulatory / IRB Submission
  - ✓ Screening / Enrollment
  - ✓ Billing Oversight
  - ✓ Data Management
  - ✓ AE/SAE reporting
  - ✓ Study Closeout
- Free consultative services
  - ✓ Protocol Review / Study recruitment strategies
  - ✓ Coordinator effort and budget analysis
  - ✓ Coordination of other institutional offices & hospital services

## **Stanford Maternal and Child Health Research Institute – Biostatistics and Data Management**

The MCHRI has partnered with the Quantitative Sciences Unit (QSU) in the Department of Medicine to provide comprehensive biostatistics and data management support, for research that is directly related to maternal and child health. This resource is available to all MCHRI members and their mentees. Projects will be reviewed for significance to maternal and child health prior to resource allocation.

The QSU is a collaborative group of over 25 data scientists including faculty and Masters- and PhD-level staff. QSU members will collaborate with investigators by lending expertise in study design, database creation, data management, and data analysis using an interdisciplinary collaborative approach. QSU members are available for collaboration, including the development of grant proposals and the implementation of funded projects.

## **Stanford Maternal and Child Health Research Institute – Stanford Children’s Health Clinical Research Support Office**

Built through MCHRI, the Clinical Research Support Office (CRSO) provides operational, informatics, regulatory, and other support for studies at Stanford Children's Health (SCH). CRSO partners with all hospital departments and School of Medicine research teams to enable the efficient and compliant conduct of clinical and translational research in maternal and child health. The primary efforts and goals of CRSO are coordinated with the Stanford School of Medicine Office of Clinical Research, Stanford University Research Institutes, School of Medicine Departments, and SCH in clinical research policy and processes. CRSO works to facilitate communication between School of Medicine research teams and hospital units and departments that are essential to supporting clinical research. The CRSO provides operational, training and informatics support to School of Medicine research teams engaged in clinical and translational research at Stanford Children’s Health.

### **Clinical Research Informatics – Stanford Children's Health**

Stanford Children's Health has designated an information systems project manager to collaborate with CRSO and assist Researchers with information system (IS) challenges for seamless execution of translational research at hospital/clinic settings. Support includes assistance with recruitment efforts using the EMR portal, designing Epic (EMR) workflows, clinical trial management in EMR including billing, collecting the data, analytics, and related support with IS security approvals. The Informatics Manager collaborates with the Privacy depts. (Hospital & SOM) and the School of Medicine Research IT for privacy guidance and efficiency in supporting clinical research.

## **Stanford Maternal and Child Health Research Institute – Drug and Device Development (D<sup>3</sup>) Service**

The Drug and Device Development (D<sup>3</sup>) service of the Stanford Maternal and Child Health Institute (MCHRI) guides breakthrough therapies through proof-of-concept studies and onto commercialization. D<sup>3</sup> supports meritorious and impactful medical products being developed by



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Stanford's maternal child health research community at any point in the development process by offering assessment, facilitation, education, and training. D<sup>3</sup> assists researchers in developing comprehensive regulatory strategy, market assessments, as well as project fundraising and business plans. Its project management guides researchers in maturing their product quickly from bench to bedside. Assessment tools support projects in their earliest phases of development and guide needs finding and concept creation. Additional services reduce barriers and project delays through dedicated IND/IDE support. The D<sup>3</sup> leverages existing Stanford Medicine research support infrastructure as well as funding and educational programs to offer robust resources for informatics, clinical operations, compliance, and training designed to reduce barriers to conducting effective translational research. These include SPARK, BioDesign, SPADA and the Innovative Medicines Accelerator as well as partnerships with Stanford's NIH Clinical and Translational Science Award (UL1 TR001085) and the Clinical Research Support Office embedded within the Lucile Packard Children's Hospital. D<sup>3</sup> sponsored education programs and seminars fill knowledge gaps in translational medicine and bring experts from the Silicon Valley innovative technology and venture capital communities to Stanford.