

**Proposal to establish  
The WOMAN and CHILD Institute  
at the University of Utah**

**Section I: Request**

The Departments of Pediatrics and Obstetrics & Gynecology propose the formal establishment of the **WOMAN and CHILD Institute** as an umbrella for developing and integrating women's and children's basic, clinical, and translational research within the University of Utah. The WOMAN and CHILD Institute will incorporate faculty career development, clinical and laboratory research, and inter-institutional administrative services.

Partnership in the WOMAN AND CHILD Institute will be open to programs, colleges, departments, and investigators within the University, Intermountain Healthcare, and other community institutions whose research efforts are related to women and children. Establishment of the Institute will formalize an inimitable partnership that will be leveraged to achieve competitive advantage in women's and children's research, funding support, health care delivery, and advocacy.

**Section II: Need**

The health of women, children and infants is a strong research focus at the University of Utah and Intermountain Healthcare. Clinical research programs include the National Children's Study, the Intermountain Injury & Research Data Coordinating Center, the Children's Environmental Health Law & Policy Center, and numerous NIH clinical research networks. Inter-departmental, laboratory based women's and children's research is concentrated on epigenetics, human genetics, neuroscience, birth defects, women's and children's environmental health, pediatric oncology, gynecologic oncology, reproductive medicine, and pharmacology.

The research environment has changed over the last decade. Successful academic research programs now incorporate multi-disciplinary teams funded through program grants, national networks, and multi-investigator awards. Clinical and translational research is integrated and supported within comprehensive research programs that require increased collaboration between academic and community based partners. Pilot funding, mentorship and development of junior faculty are important components of a sustainable research program. Current mentorship programs include the following:

- PCAT: Pediatric Clinical & Translational Scholar Program
- ISIS: Integrative Scientific Investigation Services
- CHRC: Children's Health Research Consortium Scholar Program
- CHRCD: Children's Health Research Career Development (NIH K12 grant)
- APEL: Academy of Pediatrics Education and Learning
- Research in Progress Seminars
- Annual All-Pediatrics Research Conference
- Grant Writing Retreat Workshop

The Departments of Pediatrics and Obstetrics & Gynecology actively collaborate with six colleges (Pharmacy, Law, Nursing, Health, Social Work, & Engineering), the University Library System, and five departments (Family & Preventive Medicine, Family & Consumer Studies, Biomedical Informatics, Human Genetics, Physiology) across the University and will continue to seek strong commitment and engagement with academic units on main campus.

Pediatrics and Obstetrics & Gynecology have collaborated in supporting multidimensional research efforts within the University of Utah and Intermountain Healthcare for more than 10 years, and strong institutional commitment to research is evident in both organizations. It is now clear that a large re-investment in research infrastructure is

necessary, as the infrastructure and integrating functions required to provide these essential services are currently either inadequate or duplicated at great cost across the School of Medicine and Intermountain Healthcare.

Sustained research collaboration will require institutional commitment beyond the informal relationships currently in place. Establishment of the WOMAN and CHILD Institute will bring lasting value and increased standing to the University of Utah, Intermountain Healthcare, and other community partners.

### **Section III: Institutional Impact**

The WOMAN and CHILD Institute will report to the Senior Vice President for Health Sciences and will adhere to the rules and regulations of the University. All actions of the Institute will be subject to the consent and approval of the Senior Vice President for Health Sciences.

Initially, joint executive leadership will be provided by Dr. Ed Clark of Pediatrics and Drs. Matthew Peterson and Michael Varner of Obstetrics & Gynecology. During FYs 2011 and 2012, a senior faculty member will be appointed as Executive Director to manage the operations and business affairs of the Institute. The Executive Director shall report to the Senior Vice President for Health Sciences and, as required, to the Board of Directors regarding Institute affairs. This person's scope of authority will encompass:

- oversight of key faculty and personnel
- oversight of financial processes and shared resources
- execution of research foci under direction of the SVPHSC and the Board
- identification and support of changing organizational needs and expectations
- negotiation of intra- and inter-institutional agreements related to governance, financial management, services, expectations, & commitment
- oversight of research laboratory space

The affairs of the WOMAN and CHILD Institute will be guided and directed by a Board of Directors comprised of the Chair or delegate of each participating University department or college, the Executive Director, and a senior representative of each community partner. The Board shall be responsible for the development of general policy governing the activities of the Institute within the context of University of Utah policies and will be accountable to the Senior Vice President for Health Sciences.

An Executive Committee shall be formed to provide efficiency and flexibility in management, while reserving the power of decision with respect to policy issues to the Institute Board of Directors. The primary purpose of the Executive Committee will be to oversee the Institute's day-to-day business concerns and research focus and activities. The Executive Committee will consist of the Executive Director of the Institute and senior personnel from each area of research, and will include Drs. Carrie Byington, Robert Lane, Bob Ward, and Lucy Savitz.

The WOMAN and CHILD Institute will provide a functional platform for research administration services and faculty professional development. Administrative staff within the Institute will be located within their respective departments for convenience and will collaborate with each in a virtual fashion to share resources and develop best practices. Administrative Directors, Jacquie Bernard and Erika Lindley, from Pediatrics and Obstetrics & Gynecology, will pair individuals from both departments at the managerial level to provide oversight and ensure that the needs of all partners are met. As the Institute emerges, administrative staff will co-locate upon the recommendation and approval of the Board of Directors. Proposed organizational charts are attached to this proposal.

The Departments of Pediatrics and Obstetrics & Gynecology currently have sufficient administrative office space to meet anticipated demand. To meet the requirements of an integrated laboratory research center, it is proposed that there be a consolidation of pediatric biomedical researchers into a single building. The laboratory research center will provide a unique infrastructure for inclusive, joint, and collaborative training of bench and bedside investigators.

This type of integrated approach to biomedical research is essential in today's rapidly changing research environment and is strongly encouraged by NIH and other federal grantors. The laboratory research center will be available to all investigators invested in the mission of the WOMAN and CHILD Institute, whose laboratories may be appropriately co-located.

The Department of Pediatrics currently occupies approximately 20,200 sq. ft. of laboratory space across several buildings in the Health Sciences Center and is working with the Senior Vice President for Health Sciences to identify potential sites for integrated research space. Once the new laboratory research center is established, the Department of Pediatrics will vacate lab and office space currently held in Bldg. 521 and the Wintrobe Building.

#### Section IV: Finances

Throughout FY 2011 and FY 2012, Pediatrics and Obstetrics & Gynecology will support the costs of the Institute, supplemented in part by returned overhead from the SVPHSC and with philanthropic funding. During this period, the Institute will engage Intermountain Healthcare in strategic planning discussions; Intermountain's financial support is anticipated beginning in FY 2012.

In FY 2013, financial management will shift to the WOMAN and CHILD Institute. Revenue will be derived from a variety of sources, including returned overhead on Institute grants, fixed partnership fees, fee-for-services, and philanthropic sources. Revenue from all sources will be used to support research activities in accordance with direction from the Board and in accordance with the internal policies of the partners.

Revenue will be managed by the Institute and used to support salaries, expenses, research investment, and pilot funding. All fees will be evaluated yearly and adjusted as needed and approved by the Board. A "straw-man" model to manage revenue and expense in FY 2013 is described below. The Executive Committee and Board will be fully engaged in the determination of partnership fees.

- Returned Overhead (Beginning in FY 2011)
  - Each partner will return at least 15% of overhead generated from grants held within the Institute. The amount of returned overhead will be negotiated as needed and based on Institute initiatives and budget.
- Membership Fees (Beginning in FY 2013)
  - Annual Fixed Membership Fee will be assessed to each partner for the support of fixed administrative costs.
- Flexible Fee for services (Beginning in FY 2013)
  - Fee-for-service study coordinator staffing will be available to Institute investigators.
  - Partners will purchase blocks of pre-paid time to use toward the purchase of Institute staff and services.
  - Internal pricing will apply to staff and services provided to partners.
  - External pricing will be applied to staff and services purchased by the occasional non-partner investigator.
  - A fee schedule will be developed for staff and services provided by the Institute.
  - Medicare pricing will be used for study patient procedures on research grants within the Institute.
- Philanthropic Support
  - Potential Philanthropic support has been identified by the partners.
- Pro-forma budget
  - A pro-forma budget for the WOMAN and CHILD Institute is attached to this proposal.

Significant opportunities for new research funding are foreseen as a result of establishing the WOMAN and CHILD Institute. Over the next three to five years, funding is anticipated for a Children's Health and Environmental Safety program grant, a new NIH T-32 Training grant, and two NIH RC4 Infrastructure grants to support clinical trials research. In addition, the Institute will be able to support an increased number of junior investigators in all academic and medical fields.

Based on the success with the PCAT Scholar program, it is anticipated that these junior investigators will receive an additional four to five new career development ("K") awards over the next five years. Indeed, the majority of K awards at the University of Utah reside in the Department of Pediatrics.

Integration of research administration will lead to economies of scale, increased grant success, improved regulatory compliance, and reduced organizational barriers. All Institute investigators will have access to Institute's administrative and educational support services, including grant submission and technical writing services.

Inter-institutional research will be managed via contractual arrangements specifically developed to expedite Institute-based research projects. The Board of Directors will facilitate the negotiation of appropriate contract templates to manage NIH and other federally sponsored clinical and basic research, industry funded clinical trials, and purchased services. Contracting goals include:

- Correlation of reimbursement schedules between subcontract and prime grant
- Research billing compliance systems to meet the needs of partner institutions
- Policies governing Institutional Review Boards and Privacy Boards
- Medicare pricing for study patient procedures
- Internal Institute pricing for services
- Effort reporting per NIH guidelines