Objectives of CMH Program

• The CMH program raises awareness of:
  – CMH investigators within the CCTSI of ongoing CMH research and resources
  – mechanisms for assistance to participate and succeed
  – pilot grant opportunities
  – potential collaborations with on-going research programs and CMH Working Group initiatives

• The CMH Research Program emphasizes the maternal-infant dyad, but all aspects of child health (pediatric) and pregnancy-related research are included, allowing expansion into Life Course research
Governance

Director: William W. Hay, Jr. MD
(Pediatrics/Neonatology/Perinatal Biology and Medicine/
Perinatal T32 and CHRCD K12)

Co-Directors:

Pregnancy research program:
Maternal, fetal, placental: Theresa Powel PhD
Labor & Delivery: Lorna Moore PhD

Neonatology: John Kinsella MD

Research Advocate: Vacant (Barbara Hammack helps out)

Research Nurse Manager, Perinatal CTRC: Vacant (temporarily covered by
Kim Zichterman BSN, Pediatric CTRC Manager, and Lucy Fashaw BSN,
Perinatal Clinical Lead)

Dept Ob/Gyn Clin. Research Regulatory Manager: Chanel Mansfield
Metrics: Major Accomplishments

- Development of the **Pregnancy Research Program**.
- Adaptation of the neonatal subject prioritization schema to pregnancy studies with expansion of the **Triage Committee**.
- Development of the **Perinatal Research Facilitation Committee**.
- **Establishment of a follow on research program** for the previous “Baby Blanket” that allows/promotes CCTSI Perinatal CTRC supported research projects using the **Perinatal Database and Biobank** (managed by Anne Lynch PhD and Biostatistics Core).
- Efforts to **microtize cord blood sample assays** and develop a general approach to **biosampling** (including Consent issues), both available to all investigators.
- **Clinical Research Space** in the new UCH and CHCO NICUs (still insufficient).
Pilot Projects

Funds for the CMH Pilot Awards are generously provided by the Children’s Hospital Colorado Research Institute.

- $100,000/yr (Five Projects at $20K each).
- For 2013, CHCO RI supported 9 (of 31 applications) pilot grants.
- For 2014, CHCO RI supported 5 (of 25 applications).
- For 2015, CHCO RI will support 5 (of 24 applications).
<table>
<thead>
<tr>
<th>Name</th>
<th>Institution and Department</th>
<th>Project Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>James Feinstein, MD, MPH</td>
<td>School of Medicine, Department of Pediatrics, General Pediatrics, University of Colorado Denver</td>
<td>The Degree and Duration of Outpatient Pediatric Polypharmacy</td>
</tr>
<tr>
<td>Marisa Friederich, PhD</td>
<td>School of Medicine, Department of Pediatrics, Genetics and Metabolism, University of Colorado Denver</td>
<td>Cellular transdifferentiation of fibroblasts for functional analysis of newly identified genetic causes in mitochondrial diseases</td>
</tr>
<tr>
<td>Silvia Giugliano, MSc, PhD</td>
<td>School of Medicine, Department of Pediatrics, Gastroenterology, Hepatology and Nutrition, University of Colorado Denver</td>
<td>Human Trophoblasts: Active Immunological Barrier that Prevents Transmission of Hepatitis C virus at the Maternal-Fetal interface</td>
</tr>
<tr>
<td>Rebecca Lander, PhD</td>
<td>School of Medicine, Department of Pediatrics, Nutrition, University of Colorado Denver</td>
<td>Development of research capacity to apply functional near-infrared spectroscopy (fNIRS) on infants: advancing our understanding of the role of critical micronutrients on neurocognitive development in early life</td>
</tr>
<tr>
<td>Clyde Wright, MD</td>
<td>School of Medicine, Department of Pediatrics, Neonatology, University of Colorado Denver</td>
<td>The implication of attenuated systemic inflammatory stress-induced ET1 expression in pathogenesis of persistent pulmonary hypertension</td>
</tr>
</tbody>
</table>
Child Maternal Health

Comparison of Cumulative CCTSI Pilot Award Funding and Cumulative Follow-on Funding Received by Cohort

ROI = 9.4:1

2009

ROI = 3.0:1

2010

ROI = 3.2:1

2011

ROI = 1.4:1

2012

$170,756

$159,127

$179,890

$179,286

$1,614,950

$483,250

$581,000

$250,000
Perinatal CTRC Activities

- Neonatal intensive care unit (NICU) and Labor & Delivery experienced nurses provide expert clinical research support during protocol development, implementation, and data collection
- Provide **specialized NICU nursing care (UCH, CHCO, St. Joe’s)**
  - Study recruitment
  - Instruction to research patients regarding study requirements, current clinical condition and/or disease process in relation to the study
  - Measurements: **PeaPod**, anthropometrics, Bayley evaluations
  - NICU nursing care, medication administration, patient sample collections
  - Study implementation and coordination
  - Data collection & data entry
  - Screen Labor & Delivery for pre-consented patients from clinic
    - **collect and process cord segments, cord blood, and placentas**
    - Nurse driven facilitation of the ongoing informed consent process with vulnerable populations - very skilled at this difficult task!
Perinatal CTRC Activities

• **Use of non-nurse Professional Research Assistants (PRAs) to assist with protocol implementation**
  – Increased responsibility of PRAs within their scope of practice

• **Liaisons to PIs** (actually functioning as Research Coordinators—much more than originally planned)
  – Manage protocol initiation and implementation
  – Develop guidelines & orders
  – Assist with COMIRB renewals/approvals
  – Troubleshoot nearly all problems
  – Provide education and training to clinical staff
  – Ensure compliance with regulatory requirements
  – Collaborate with clinical teams to develop a plan of care for coordination of research procedures
2014 Neonatal-Perinatal CTRC Activity

• Increased FTE’s from 5.4 to 7.1 by changing CTRC staffing model
  • Fully staffed with 5 RNs including the Clinical Lead, 2 PRAs, and 1 Program Coordinator.
  • RNs maintain clinical acumen by staffing in the NICU
  • Increased PRA FTEs to offset non RN tasks
  • A Program Coordinator added to support the subsidized fee for service business model
• Restructured role & responsibilities of PRAs as delegated by RNs
• PRAs functioning as liaisons for observational protocols
• Maintained RedCap database to manage protocols’ census and Perinatal activity
  – Utilized QI capabilities of REDCAP to improve documentation and accuracy of data
  – Improved definitions of research responsibilities to better capture time allocated to each protocol
Perinatal CTRC Activity

Manage 27 protocols: 6 NICU, 18 L&D, & 3 Newborn Nursery

- 10 studies had a combined L&D and NICU/Nursery component
- Cord blood and placental collections are among the most difficult of L&D protocols: 24% eligible, 34% enrolled, and a total collection rate of 80% (up from 77%)
- The Perinatal CTRC had contact with 51% (down from 60%) of eligible patients on L&D
  - Staff turnover
- Overall, new subject enrollment rate is 38% of eligible patients
  - Increase in enrollment from prenatal clinics by individual research teams
  - Less patient enrollment with more labor intensive protocol procedures per subject
  - Completion and/closing of major research protocols
2014 Activity

- **2171** “visits”; a 17% increase from 2013
- **1398** contact hours; a 23% increase from 2013

- Increased activity is a result of change in enrollment criteria, pre-consented subjects in clinic, protocol overlap (**MFMRU collaboration**), and personnel changes
- Perinatal activity is not always captured as a visit; majority of work is facilitation and coordination of study protocols and education of investigators
- Maintained coverage at 3 hospitals with **24/7 availability**, which is unpredictable.
Dr. Hay was former voting member of the National CTSA Consortium’s Child Health Oversight Committee (CC-CHOC), a member of the CC-CHOC Operations Committee, and inaugural chair and organizer of the Life Span Working Group. In addition, Dr. Hay established the Alliance Society Status of the CC-CHOC with the Pediatric Academic Societies Program Committee (future of this is uncertain, but the PAS meeting will continue to support Pediatric Clinical-Translational Research Program). Dr. Hay now is a member of the new CTSA Lifespan Domain Task Force.
Response to Critique from 2014 EAC Review

Nothing asked.
Plans for Next Year

• Stabilize Perinatal CTRC Research Nursing Support (shift burdensome night/weekend call to others).

• Expand the CMH Pilot Program—encourage applications.

• Ensure that there is a single COMIRB panel for pediatrics and maternal-fetal-neonatal research

• Fill vacancies: Perinatal CTRC Research Manager (in process); Perinatal Research Advocate
CMH Research Advocate—
A special person for special populations with unique needs.

• The Child and Maternal Health Program (CMH) wants to assure that all research we support is of the highest scientific and ethical quality. The Research Advocate (RA) serves two functions.

• The CMH RA works with investigators and advises about study design and conduct to assure that the research is of high scientific quality and that the research adequately protects all research participants. Researchers should visit Research Advocacy: For Investigators to find out how the RA can help you and your research.

• The CMH RA’s most important function is to be a contact person for all research subjects who have questions or concerns and to design and implement programs to improve participant understanding of research. Research participants, or individuals who are thinking about being in a research study, should click on Research Advocacy: For Participants to find out how the RA can you as a participant, contact information, and access to many resources and useful materials.
Plans for Next Year

• Re-develop the essential attributes of the Baby Blanket Program: Recruitment for all; Perinatal Data Base; Biobank. Need to be CCTSI and campus resources.

• For now—Anne Lynch will maintain a committee to review applications (all sources) for use of stored perinatal data and biosamples (supported by the Biostatistics Core).

  • Approximately 25,000 records in the database
  • ~20,000 longitudinal plasma samples and ~4,000 longitudinal DNA samples, all paired with data.

• Charges to investigators for this service.

• We will advertise this service through the CMH-CCTSI website.
Questions for EAC

- **Competition, Triage and Facilitation:** How should we deal with the Ob Department NICHD MFM RU and its restriction of all eligible pregnant women (and fetuses and neonates depending on protocol) to their protocols, which could severely limit research with these subjects for the entire campus (e.g., Ob, Neonatology, Pediatrics, Nursing, Dentistry, Pharmacy, Public Health, School of Medicine, etc.)?

- Should there be a budget for services other than the Perinatal CTRC, such as a Perinatal Research Advocate and the Perinatal Research Subject Recruitment Program and the Perinatal Database (formerly the Baby Blanket Program)?

- Is there now sufficient national CTSA pediatric/child-maternal health activity to warrant further developing and formalizing ours?

- How would you recommend getting more Pilot Grant applications?