Name of CRU: Children's Clinical Research Unit (CCRU)

Date: January 3, 2014

1. **Scope of Research within the CCRU:**

   The CCRU is responsible for oversight of all research involving human subjects that requires Institutional Review Board approval and is conducted by faculty members within the Department of Pediatrics.

2. **Key Personnel:**
   - **Director:** Thomas R. Kinney, M.D.
   - **Assistant Director:** Blythe Devlin, Ph.D.
   - **Research Practices Manager:** Tara McKellar, R.N., B.S.N.
   - **Financial Practices Manager:** Christeen Butler
   - **Assistant Research Practices Manager:** Kathy Auten, MSHS CRA

3. **Define Clusters and Leadership within Clusters.**

   ![Children's Clinical Research Unit Organizational Chart](chart.png)
The Chair of the Department of Pediatrics appoints the CCRU Director and the Advisory Board Members.

The CCRU Director is responsible for the conduct of the CCRU.

The CCRU Assistant Director reports to CCRU Director. The Assistant Director will work closely with the Director. The Assistant Director will review protocols, assist study teams in preparing needed study documents, work with the Research Practice Manager and Financial Practice Manager to conduct reviews of CCRU projects.

The CCRU Financial Practices Manager has a dual reporting relationship to the CCRU Director and to the Department’s Chief Administrator. Divisional Administrators have dual reporting relationship with respect to their responsibilities related to clinical research. The Divisional Administrators report both to their Division Chief and to the CCRU Financial Practices Manager.

The CCRU Research Practices Manager reports to the CCRU Director. Research Coordinators and other research support staff employed by divisions have a dual reporting relationship to the PI/Division Chief and to the CCRU Research Practices Manager.

The CCRU Assistant Research Practices Manager reports to the Research Practices Manager. The Assistant Research Practices Manager will work closely with the Research Practices Manager and assists in the preparation of IRB materials and is responsible for pre-IRB reviews and serves as primary liaison to other research organizations within the Health System.

### 4. Faculty Advisory Board

<table>
<thead>
<tr>
<th>Standing Members</th>
<th>Role</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thomas R. Kinney, M.D.</td>
<td>Chair</td>
</tr>
<tr>
<td>Daniel Wechsler, M.D., Ph.D.</td>
<td>Chief, Hematology-Oncology</td>
</tr>
<tr>
<td>Colleen Cunningham, M.D.</td>
<td>Chief, Infectious Diseases</td>
</tr>
<tr>
<td>Jennifer Li, M.D.</td>
<td>Research Chief, Cardiology</td>
</tr>
<tr>
<td>Kay Marshall</td>
<td>Chief Administrator for Pediatrics</td>
</tr>
</tbody>
</table>

**Consultants**

|Danny Benjamin, M.D., Ph.D.  | Biostatistics |
|Phil Rosoff, M.D.            | Ethics        |

**Ad Hoc**

|Ira Cheffetz, MD             | Interim Chair, Pediatrics                 |

Advisory Board members are appointed by the Chair of Pediatrics. Members serve two year terms on the Board. The Advisory Board is chaired by the CCRU Director and meets regularly. In addition, the CCRU Director may consult or call more frequent meetings of the Advisory Board related to the review of specific proposals or on-going clinical research projects.

**Function:**

- Advise CCRU leadership on the appropriateness of clinical research projects
- Advise the CCRU on the feasibility of specific projects in light of Departmental/Divisional financial constraints, resource availability and allocation
- Provide advice regarding the appropriate distribution of margin between support for CCRU expenses, unfunded Department research, and Principal Investigator (PI) discretionary funds
- Review clinical research projects where there is potential for conflict of interest involving either the individual or the institution or untoward fiscal consequences to the PI or Department
- Review the CCRU research portfolio
5. **CCRU Governance and Financial Plan:**
As described in Item 3, the CCRU reports to the Chair of Pediatrics. Funding for the CCRU Administration currently comes from the Department. Clinical research expenses are back stopped by a combination of money generated from trials, faculty discretionary funds, divisional discretionary funds and department funds.

6. **CCRU Stakeholders:**
The CCRU supports the pediatric research work of external organizations and faculty, departmental faculty members, research coordinators and staff members engaged in clinical trials requiring consent of the human subject.

7. **Communication Plan:**
The CCRU will be responsible for maintaining an accurate record of all studies PIs, CRCs, and Grant Administrators in the Department of Pediatrics. The primary responsibility for managing this is with the CCRU Financial Practices Manager and Research Practices Manager. This will be accomplished through personnel records maintained in the Chair’s Business Office but will also require Division Administrators to insure that the CCRU is aware of any personnel changes involving research staff in their respective divisions.

Any research information transmitted to the CCRU regarding research practice or financial management of studies will be forwarded, as appropriate, to all PIs, CRCs, Divisional Grant Managers, and Divisional Administrators throughout the Department. If information to be transmitted is research practice, regulatory, or quality assurance-related, the Research Practices Manager will communicate this information to all individuals involved in research. Likewise, if information to be transmitted is financial or administratively focused, the CCRU Financial Practices Manager will communicate this information to all individuals involved in research. On occasion, the CCRU Director or the Chief Administrator of the Department may communicate information that may have a more global application than specifics regarding research.

Investigators, CRCs, research support staff, Divisional Grant Managers, and Divisional Financial Administrators are expected to communicate any questions, concerns, issues, and modifications to original study plans with the appropriate personnel within the CCRU. Any communications with sponsors that potentially result in study changes or financial arrangements will be related.