Washington University in St. Louis
Institute of Clinical & Translational Sciences

Center for Applied Research Sciences
& Regulatory Support Center

Effective Research Management Fair
March 27, 2008

John Newcomer, M.D.
Director – Center for Applied Research Sciences, Clinical Trials Unit
Co-Director – Regulatory Support Center
Professor, Psychiatry

James A Moran, JD, CPA
Operations Officer – Center for Applied Research Sciences
Co-Director – Regulatory Support Center
Assistant Dean Clinical Trials
Center for Applied Research Sciences (CARS)

CARS Director
S. Klein, MD

Scientific Advisory Committee

CARS Administrative Core
Administrator: C. Acree
Operations Officer: J. Moran, JD, CPA

Recruitment Enhancement Core
Co-Directors: S. White, C. Rathmann

Clinical Trials Unit
Director: J. Newcomer, MD

Intensive Research Unit
Director: S. Klein, MD

Pediatric Research Unit
Director: N. White, MD

CARS Resources
• Consultation Services and Protocol Review
• Study Protocol Resource Tracking and Management
• Research Nursing Services
• Bionutrition Core
• Special Chemistry Core Laboratory
• Human Physiology Core

Brain, Behavior and Performance Unit
Director: J. Perlmutter, MD

Institute of Clinical and Translational Science Resources
• Design, Biostatistics and Research Ethics
• Bioinformatics Program
• Program in Human Genetics and Genomics
• Programs for the Development of Novel Methodologies and Pilot Collaborative Studies
• Translational Technologies and Resources
• Regulatory Knowledge and Support Program
• Center for Clinical and Translational Research Training
• Center for Community Based Research

Center for Clinical Imaging Research
Director: M. Mintun, MD

Washington University Resources
• Biodefense and Emerging Disease Center
• Center for Aging
• Center for Cardiovascular Research
• Center for Genomic Sciences
• Children's Discovery Institute
• Clinical Nutritional Research Unit
• Diabetes Research and Training Center
• Digestive Disease Research Center
• Interdisciplinary Research Careers in Women's Health
• Siteman Cancer Center
Research Units Staffing and Use

**Intensive Research Unit (IRU) – 4th & 5th floor Barnard**
Staff: 17 RN’s, 1 RN Tech, 1 Med Asst, 3 Bionutritionists, 2 Dieticians, 2 Research Dietetic Assist, 4 Diet Techs
Visits/yr: 600 inpatient, 5000 outpatient

**Clinical Trials Unit (CTU) – 11th floor CAM**
Staff: 12 RN’s, 1 Med Assist, 2 LPN’s, 2 Data Coordinators
Visits/yr: 7,500 outpatient

**Pediatric Research Unit (PRU) – 11th floor SLCH**
Staff: 3 RN’s, 1 Med Assist, 0.5 Bionutritionist
Visits/yr: 2000 outpatient
Research Units Staffing and Use

**Regulatory Support Core - Suite 301 IWJ**
Staff: 2 JD’s, 4 RN’s, 3 Contract Specialist, 2 Admin Assistants
Protocol Development Support, Billing Compliance, Pharma Contracts, Concierge / Match Making, Assistance with IRB submissions / renewals

**Participant Recruitment Core – 301 IWJ & BJH Lobby**
Staff: Medical Director, 2 Co-Directors, 5 Recruit. Coord.
Develop Recruitment Plan, Track Target vs. Actual, VFH Database w/ 27K volunteers

**Advocacy and Ombudsman Core – Suite 301 IWJ**
Staff: 1 RN, 1 Assistant
Develop QA / QI plan for CARS and assure compliance w/ GCP and IRB regulations
Efforts to Facilitate and Enhance Research

**Improved submission process of research protocols**
- Process streamlined and harmonized with IRB.
- Developing a single submission process for both CARS and IRB.
- Developing web-based “Request for Services Form”

**Improved scientific review of submitted protocols**
- Increased focus on modifiable protocols.
- Improved biostatistical review (lead to biostatistical input at onset of study design and before grant application?)

**Acquisition of improved technology**
- Institutional funds obtained to purchase an iDXA

**Improved Support for PI-initiated Clinical Trials**
- Developing a library of protocol & consent language
- Staffing to work with PI’s to help navigate complex requirements
Efforts to Facilitate and Enhance Research (in development)

**Uniform electronic data capture system**
Efficient mechanism for capturing common data elements across protocols.

**Clinical Studies Management System**
(collaboration with Johns Hopkins University)
Common IT infrastructure for clinical research budgeting, billing compliance, participant recruitment and electronic data collection.

Cost of this system provided by Washington University and Barnes-Jewish Hospital

**Pediatric Research Unit**
Assessment of space, services, future needs (leadership of CARS, major research themes in Pediatrics, K12 and K30 junior faculty)
Comprehensive space plan to collocate the IRU and CTU (plus many other ICTS components) to 55,000 square feet of newly renovated space on 4 contiguous floors of a building in center of hospital complex.

PRU space plan being discussed with St. Louis Children’s Hospital
## Key Contacts

<table>
<thead>
<tr>
<th>Name</th>
<th>Title</th>
<th>Role</th>
<th>Contact Info</th>
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</thead>
<tbody>
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