

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

Center for Applied Research Sciences  
& Regulatory Support Center

Effective Research Management Fair

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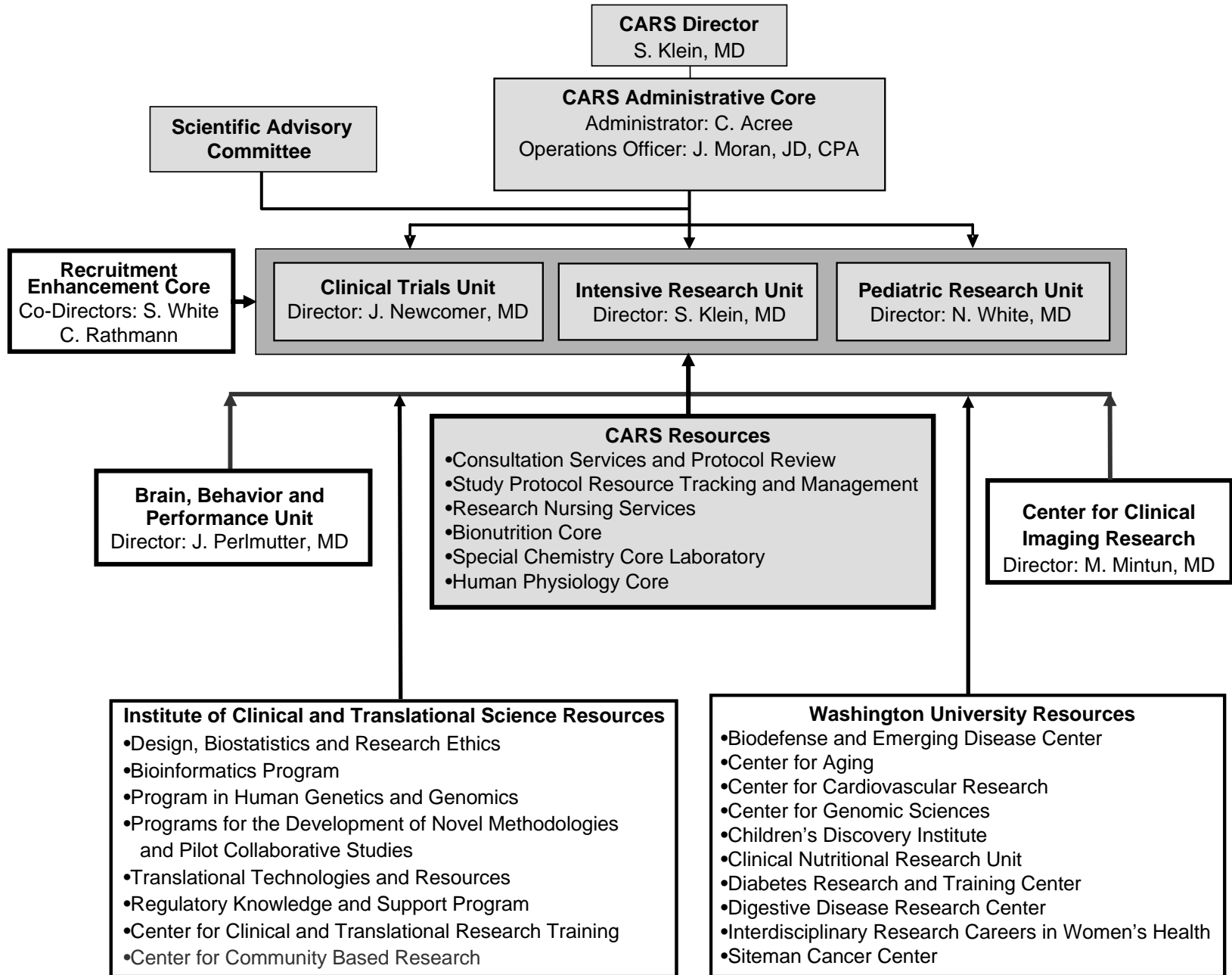
James A Moran, JD, CPA

Operations Officer – Center for Applied Research Sciences

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Assistant Dean Clinical Trials

# Center for Applied Research Sciences (CARS)



# Research Units Staffing and Use

## **Intensive Research Unit (IRU) – 4<sup>th</sup> & 5<sup>th</sup> 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) – 11<sup>th</sup> floor CAM**

**Staff: 12 RN's, 1 Med Assist, 2 LPN's, 2 Data  
Coordinators**

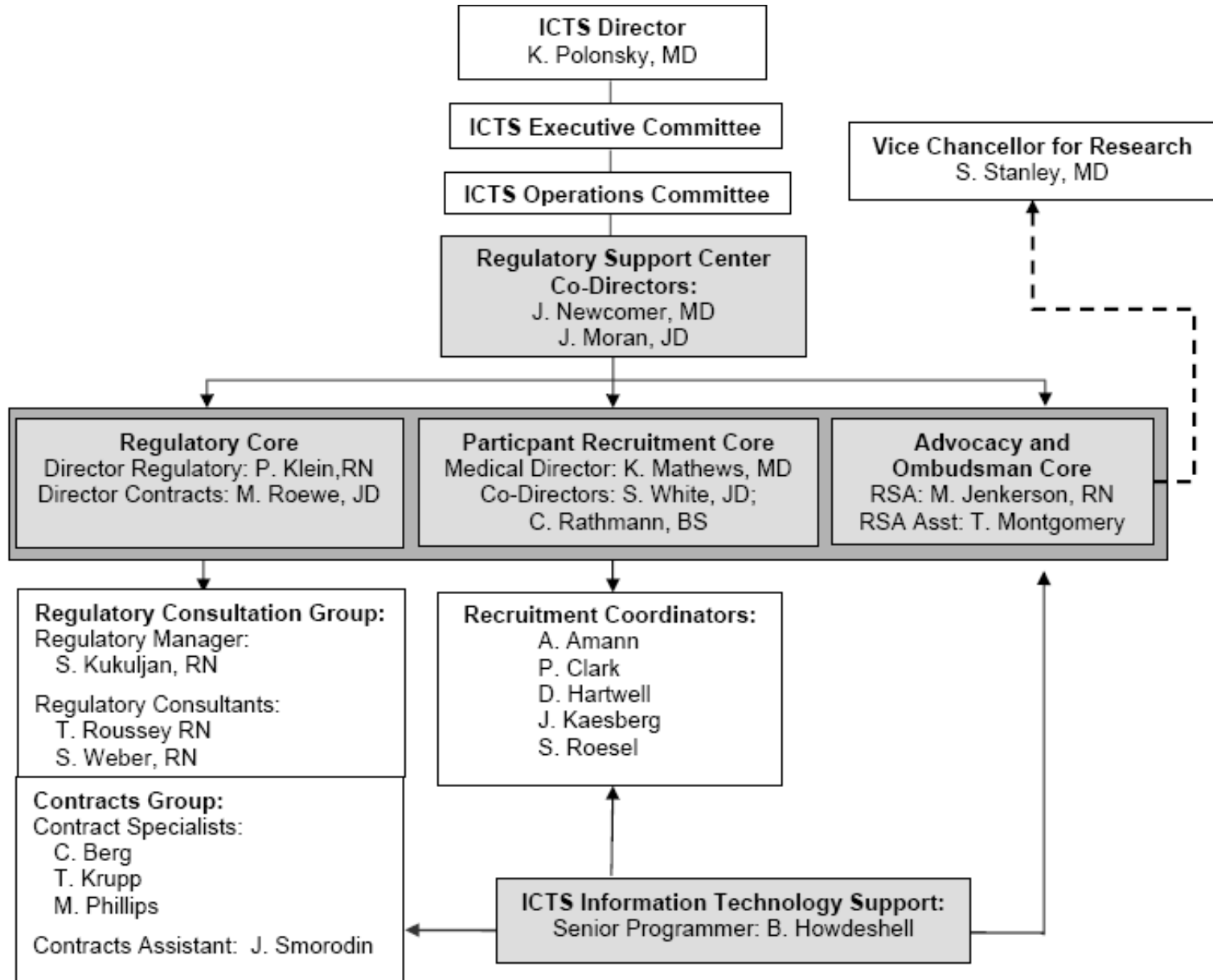
**Visits/yr: 7,500 outpatient**

## **Pediatric Research Unit (PRU) – 11<sup>th</sup> floor SLCH**

**Staff: 3 RN's, 1 Med Assist, 0.5 Bionutritionist**

**Visits/yr: 2000 outpatient**

# Regulatory Support Center



# 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)

# Space: The Final Frontier



**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

Name	Title	Role	Contact Info
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