PLDP project: Developing a Central Pediatric Clinical Research Coordinator Pool Program

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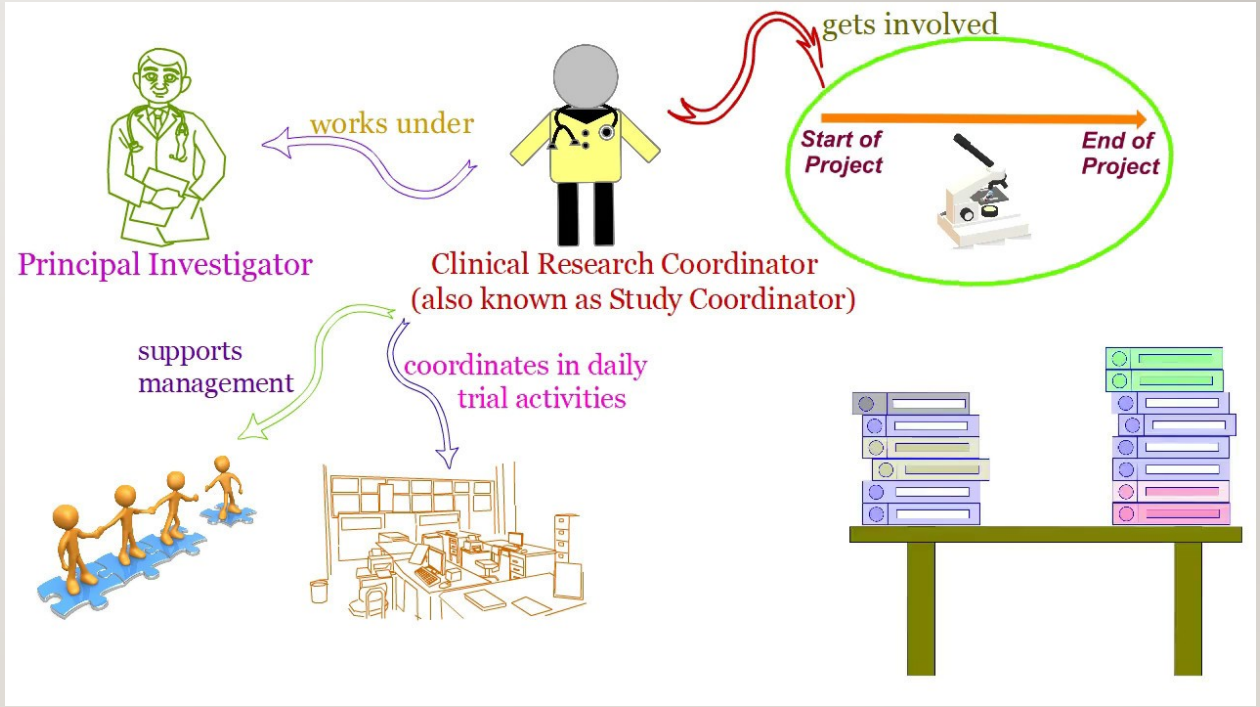
THE RATIONALE

- Many investigators, especially in smaller divisions, may have studies that need a partial FTE of a Clinical Research Coordinator (CRC), but cannot support a full FTE
- While bigger divisions may have enough CRCs to divide up such studies, even they need help
- Our existing Pediatric Clinical Research Unit (PCRU) has limited capacity
- Our WashU's commercial Center for Clinical Studies (CCS): limited capacity, discomfort with pediatric studies
- Fiscally more efficient than current structure
- Will smoothen out the ebbs and flows in research studies

IS THERE A NEED?

- We polled all WashU Peds division chiefs:
  - 6 said they would use
  - 2 more likely don't recognize their existing need (per our Department Chair)
- We have lots of junior faculty who can benefit, though others could too.



PROPOSED STRUCTURE

- Based off model at Vanderbilt called Center for Clinical and Translational Research (CCTR), sponsored by Chair Steve Webber, headed by Professor Jay Wilkinson
- They started small in 2016, with 2 CRCs (one of them also performing the manager role), funded through new the Dept. Chair's start up package, initially with 4 industry studies.
- They ramped up slowly to now where they have run 33 industry studies and 2 NIH subcontracts, for 7 different divisions, now up to 4 CRCs and a separate manager, revenue now $350k/yr.

MENU BASED OFFERINGS

- IRB and regulatory, site monitor visits, billing grid, maintaining research records
- Study coordination, screening eligible subjects, shipping kit storage, sample shipping
- Core services (echo and imaging), picking up drugs from investigational pharmacy
- Sophisticated time management and invoicing system (Harvest Project Management)
- Residual revenue sharing between CCTR (50-60%), division chief and study PI
  - Different than WashU CCS

NOT PART OF THIS SERVICE

- Subject consenting (done by PIs)
- Phlebotomy and sample storage processing (handled by their separate Pediatric CRU)

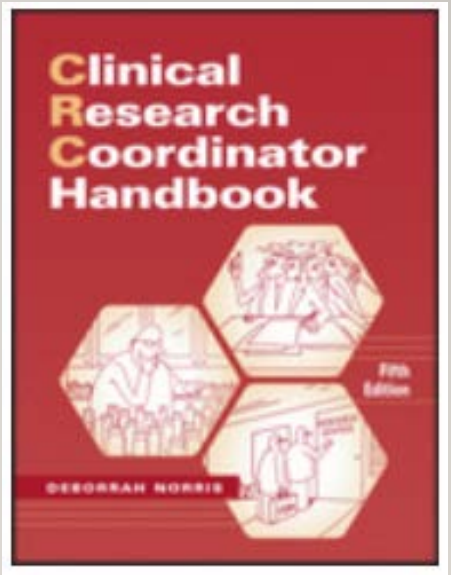
FINANCIAL STRUCTURE

- Initially fully supported by Dept. for first 2 years, then partially self-supported since then
- Faculty supervisor Jay Wilkinson started with 25% effort to develop, now down to 20% to run
- Charge master creation was the biggest job (they have sent us their current charge master)
- Creation of job descriptions (Jay has these)
- Space needed by this service for cubicles and to store records and shipping kits

Regulatory Preparation and Processing Fee	$ 3,150.00
Essential Document Preparation Fee	$ 1,050.00
Budget and Contract (Payment Terms) Preparation Fee	$ 2,100.00
Scientific Review Committee Fee	$ 2,100.00
Indirect Cost Rate @ 35%	2,924.25$
*** Total Due upon execution of Contract ***	**$11,279.25**

KEY DIFFERENCES FOR OUR PROPOSED PROGRAM

- Not limited to funded industry or NIH studies;
  - We want to support some unfunded investigators
- We would need a scientific proposal review board for the investigator-initiated studies
  - Need to identify a long term leader for the central CRC pool program
- Proposal for existing CRCs to donate time to the pool
- We could potentially offer this service pediatric divisions housed in other departments (Neurology, Orthopedics, Radiology, ENT)
- Creation of an onboarding rapid training program within Pediatrics for CRCs



INTERACTIONS WITH OUR PCRU AND ICTS

- Our WashU PCRU: 2.75 FTE CRC, of which 10-25% effort is outside the PCRU
  - This new program could be separate from PCRU or as an expansion of PCRU (our current PCRU head's preference)
- WashU ICTS:
  - Provides partial salary support for PCRU manager
  - Also provides partial support to commercial CCS
  - Senior CRC from this proposed program could attend campus level clinical trial meetings and coordinate with our Dept. and our Children's Hospital

ACKNOWLEDGEMENTS

- Gary Silverman, my Dept. chair
- Julie Bubeck-Wardenburg, my colleague chief of CCM
- Steve Webber (my PLDP mentor)
- Jay Wilkinson, head of CCTR