Centralization/Reorganization of Clinical Research Support

Pragmatic Approach

Presented to the Clinical Center Research Hospital Board

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Background

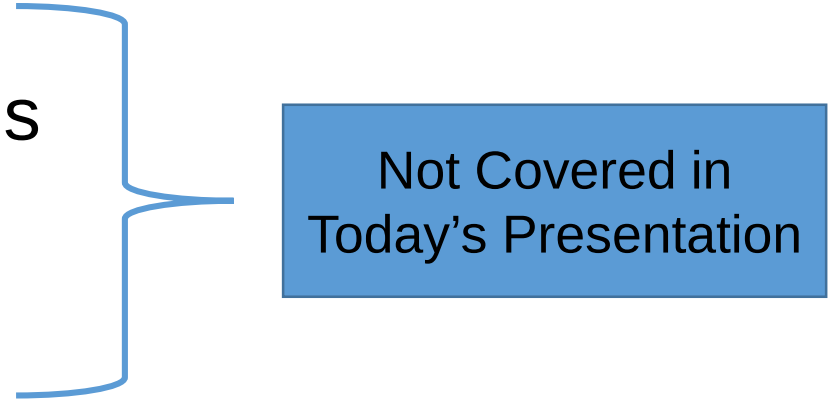
- Initial proposal by Dr. Lane
- Multiple revisions by Dr. Gottesman’s office
- Multiple Wednesday afternoon meetings
- Meeting with Drs. Tabak & Collins
- Meetings with CC Nurses led by Dr. Wallen
- Meeting With Drs. Henderson & Guptill
- Meeting with Dr. Zoon
- Too many other 1-on-1 meetings to mention

Assumptions

- Relief from hard hiring freeze with implementation instructions will occur
- Procurement of enterprise IT system for administrative support of research will proceed
- DDIR will continue to focus on policy vice operations

Organizations Impacted

- Clinical Center
- I/C's – especially those that have little organic support for clinical research
- DDIR
- IM/IT systems
- OHSRP
- ORSC



What Are We Trying to Accomplish?

- Build a culture of quality while facilitating compliance
  - compliance with FDA regulations
  - compliance with AAHRP, ORP, & OHSRP regulations and policies
  - compliance with HHS & NIH policies and regulations
- Reduce gaps in clinical research support between larger institutes and smaller institutes
- Facilitate clinical research – especially for early investigators
- Separate policy and operations
- Improve patient safety and clinical quality at the same time that clinical research support is enhanced

Pragmatism

- Influence vice control
- Functional equivalency - not everything will be the same for everybody
- Generic protocol services / specialized services

Influence vice Control

- Original proposal (Lane paper)

  Hospitalists for every in-patient unit

  CC Consultants reporting to CEO outright (vice IC)

  Alternatively, a large number of MOU's would need to be written - specifying understanding that when functioning as consultants the physicians would be working for the CEO

- First option is very expensive
- Second option is extremely high maintenance

Step 1 – Primary Nurse Model

- Based on current OP 8 model. 1 CC nurse per 125 patients.
- Every patient has a ‘primary nurse’ analogous to patients in managed care plans who have a PCM – separate from research protocol
- Requirement not as large in clinics that see patients on consultation (model based on the primary protocol clinic)
- Re-purpose nurses extant in the clinics already

Primary Nurse Model

- Really an old model brought back to life
- OP 8 and OP 4 already covered. OP 11 has enough nurses to implement the model
- NHLBI and NCI (medical oncology) – primary nurse model is less applicable, not included (functional equivalency)
- NCI (surgical oncology) included
- Dental and eye clinics are primarily consult clinics (still will get 1 additional nurse in the model)
- OP 9 and pedes clinic (OP 1) have the largest requirements

New FTE Requirement 16.5

Step 2 CC Research Support Office

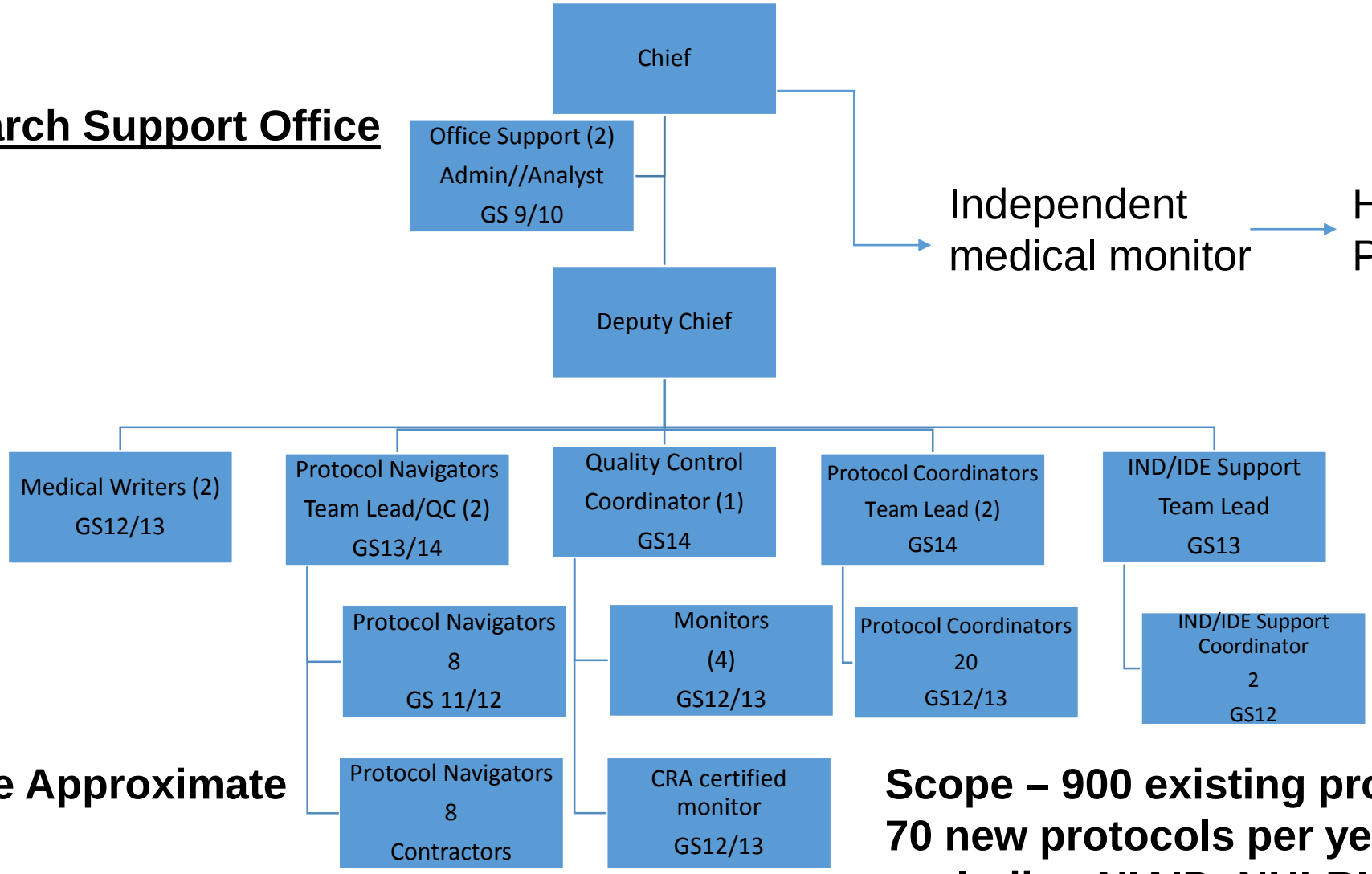
1. Protocol navigators
2. Protocol writers
3. Protocol monitors (site monitoring)
4. Study coordinators

Generic Services

5. Independent safety oversight with independent medical monitor
6. IND / IDE office (regulatory support)
7. Statistical support
8. Data management support

More Specialized Services

CC Research Support Office



All Numbers Are Approximate

Scope – 900 existing protocols, 70 new protocols per year excluding NIAID, NHLBI, & NCI

Integrated Patient Safety (Clinical & Research)

- 2, 3, or 4 independent opportunities to detect adverse events, unanticipated problems, or protocol deviations
- Primary nurse
- Patient safety & clinical quality office
- CC Clinical Research Support Office
- Research team
- NCI medical and NHLBI – 2 independent opportunities (research team and patient safety and quality office)
- NIAID – 3 (primary nurse, research team, patient safety and quality office)

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