CTEP Workshop

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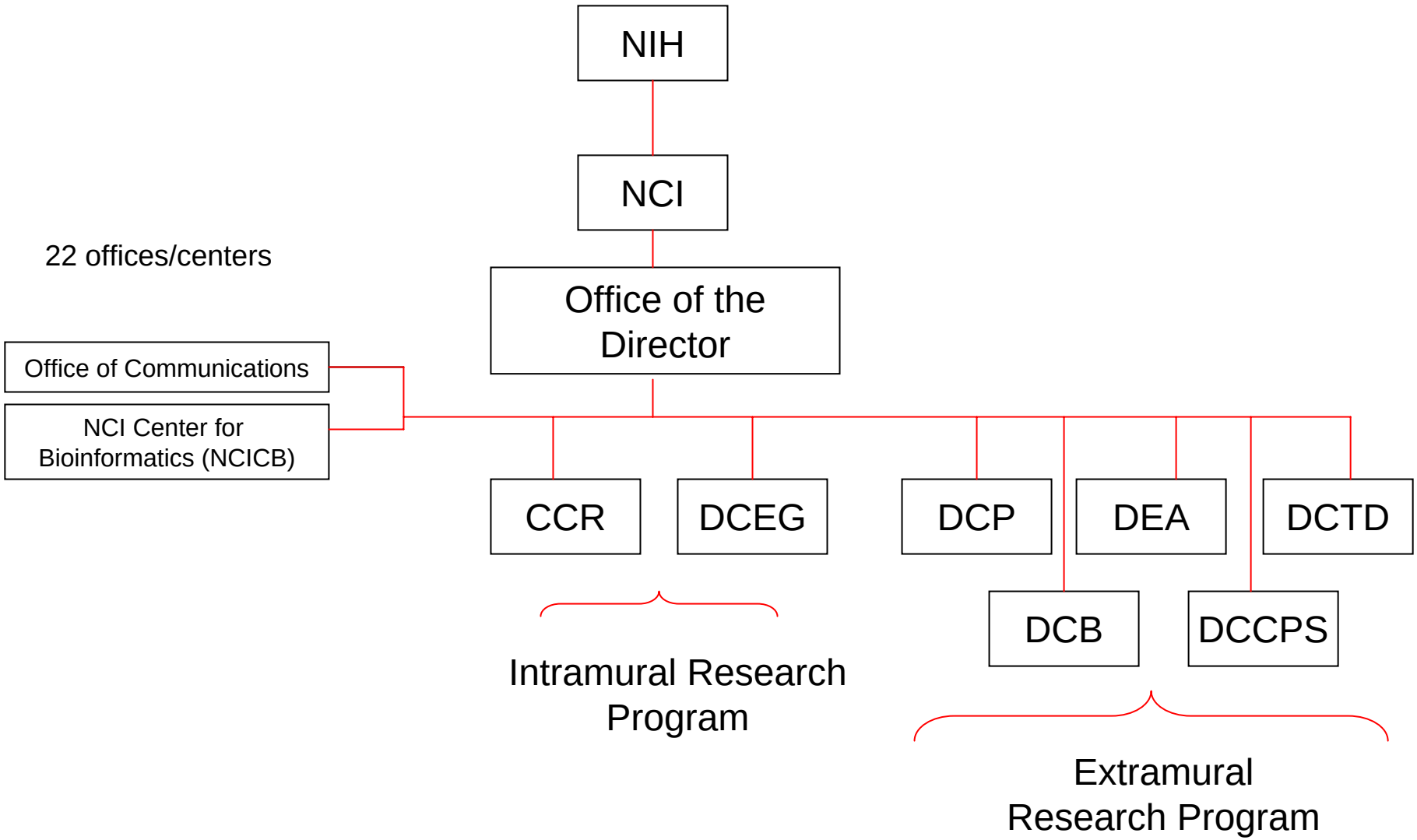
Workshop Objectives

- At the end of this workshop, participants will be able to:
  - Discuss the roles of each of the six (6) branches within CTEP
  - Discuss the role of CTEP's Protocol and Information Office (PIO)
  - Discuss the life cycle of a protocol from LOI/Concept to study closure
  - Discuss CTEP's adverse event reporting guidelines
  - Discuss CTEP's Clinical Trial Monitoring and On-Site Audit Program
  - Identify the three (3) types of CTEP Codes and how to report data against the codes

An Overview of the NCI's Cancer Therapy and Evaluation Program (CTEP)

NCI Organizational Structure



DCTD Programs

- Cancer Diagnosis Program (CDP)
- Cancer Imaging Program (CIP)
- **Cancer Therapy Evaluation Program (CTEP)**
- Developmental Therapeutics Program (DTP)
- Radiation Research Program (RRP)
- Biometric Research Branch (BRB)
- Office of Cancer Complementary and Alternative Medicine (OCCAM)

CTEP's Mission

To improve the lives of cancer patients by finding better ways to treat, control and cure cancer.

How CTEP Accomplishes This Goal

- Identify new agents and approaches to treatment
- Introduce these new agents to Clinical trials
- Evaluate the new agents
- Compare standard therapy vs. new therapy
- Collaborate with industry, Cancer Centers, and Cooperative Groups

CTEP's Responsibilities…

- Create development plan for Investigational agents and Preparing and submitting Investigational New Drug Applications (INDs)
- Interact with biotech and pharmaceutical companies and preparing agreements for clinical development of agents
- Provide funding opportunities for cancer clinical research

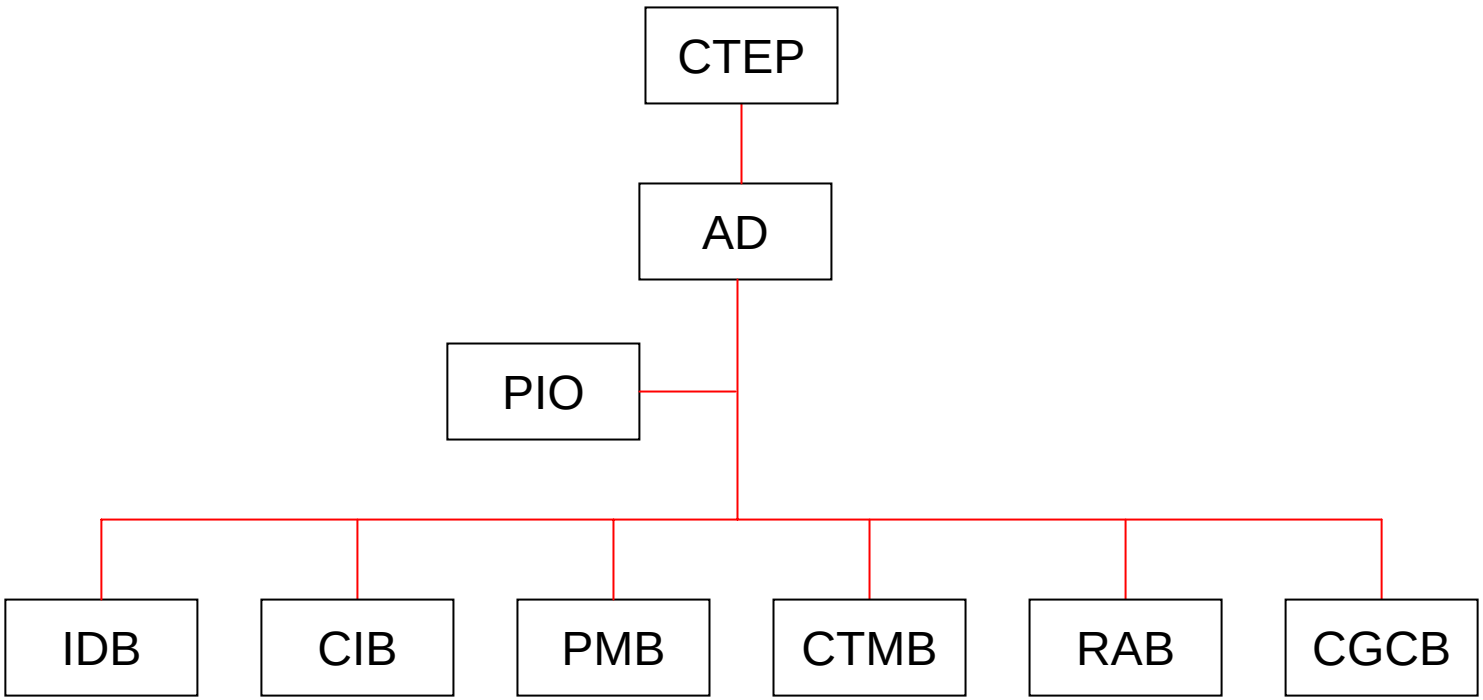
…CTEP's Responsibilities

- Manage all documentation related to DCTD-sponsored clinical protocols
- Distribute investigational agents for use in DCTD-sponsored clinical studies
- Monitor regulatory compliance for DCTD-sponsored trials

Advantages of Collaborating with CTEP

- Regulatory expertise
- Evaluation of agents in a variety of tumor types and disease settings
- Expedited clinical trials through a network of cooperative groups and cancer center and Phase 1 & 2 contracts

CTEP Organization Chart



Investigational Drug Branch (IDB)

- Drug Specialists (Main focus is drug-oriented)
  - Create drug development plans (Phase I and II trials) for both chemo and biologic agents and coordinate with industry and academic sources
- Solicit, review and prioritize trials (LOI Process)
- Monitor trial conduct, response and adverse events
- File ISRs and annual reports to FDA for all CTEP-held INDs

Clinical Investigations Branch (CIB)

- Disease Specialists (Main focus is disease-oriented)
  - Develop, organize, and review investigational programs to evaluate the comparison of specific
- Coordinate the Clinical Trial Programs
  - Cooperative Groups and International planning of Phase 3 trials
- Specimen Banking
  - Coordinates the collection, banking, and use of clinical specimens and the procedures for utilizing these specimens type and methods of cancer therapy

Pharmaceutical Management Branch (PMB)

- Coordinate Investigator registration
- Provide inventory management and world-wide distribution of Agents
  - Drug forecasting, acquisition and Inventory of all IND agents distributed by the for all CTEP INDs
  - Authorization and distribution of all NCI-sponsored IND agents to eligible investigators
- Authorize and process all requests for Special Exemption and Group C protocols
- Oversee the Treatment Referral Center (TRC)

Clinical Trials Monitoring Branch (CTMB)

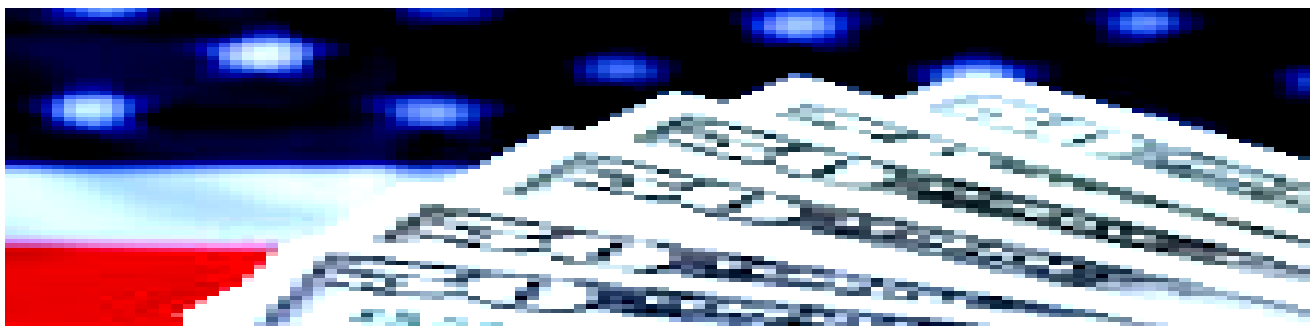
- CTEP's human subject protection and informed consent experts
  - Assure CTEP/NCI sponsored clinical trials are conducted in compliance with protocol, GCP and Federal regulations
- Conduct on-site audits of all clinical trials sponsored by CTEP and recommend any action or sanction if necessary
- Coordinate special response audits of pivotal clinical trials
- Oversee the Clinical Trials Monitoring Service (CTMS) contract

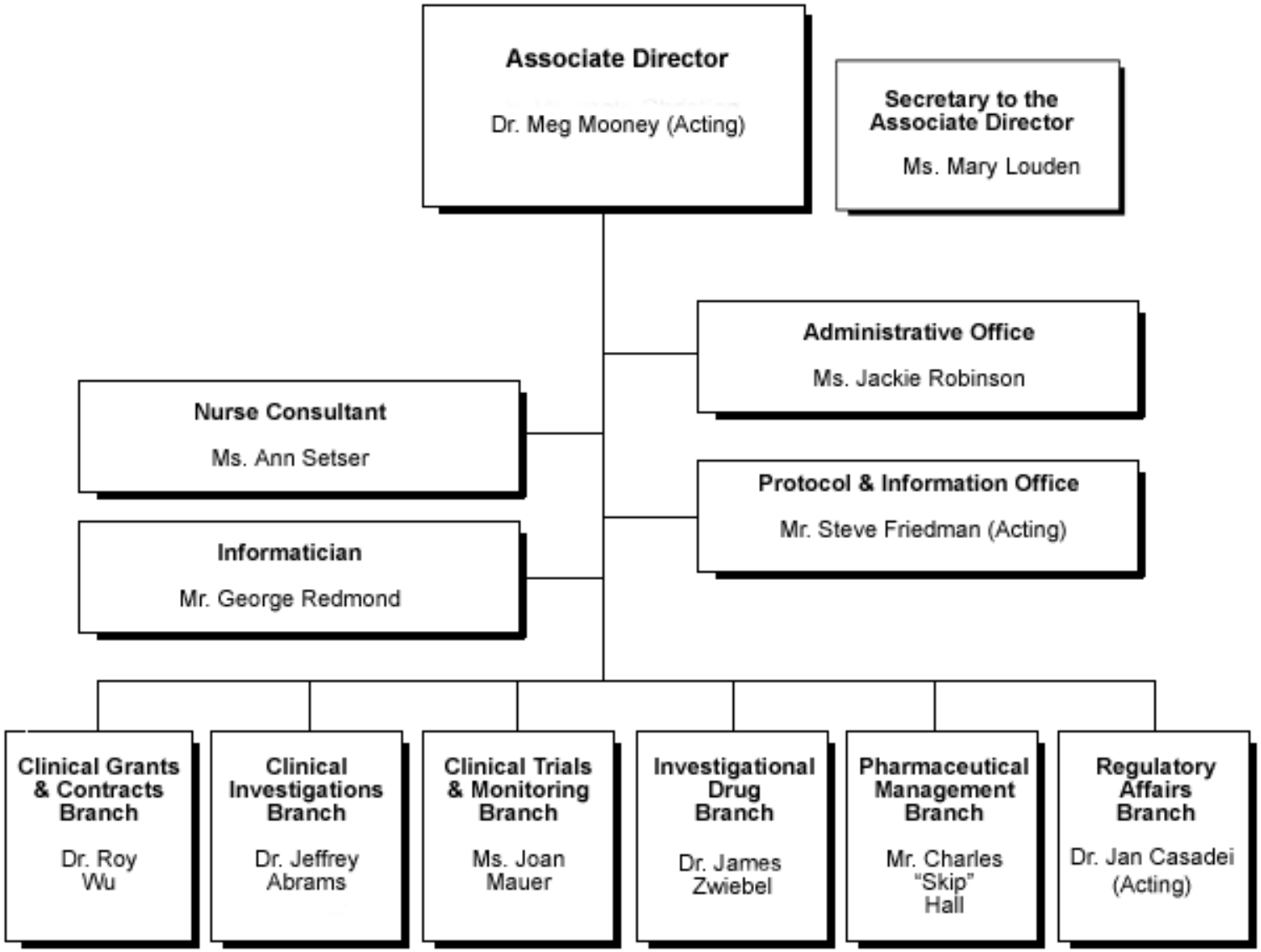
Regulatory Affairs Branch (RAB)

- Liaison to the FDA: CDER and CBER
- Prepare and submit Investigational New Drug Applications (INDs)
- Prepare agreements for clinical trials for co-development of investigational agents with industry collaborators
  - Clinical Trials Agreements (CTAs)
  - Cooperative Research and Development Agreements (CRADAs)
- Coordinate NCI and industry interactions

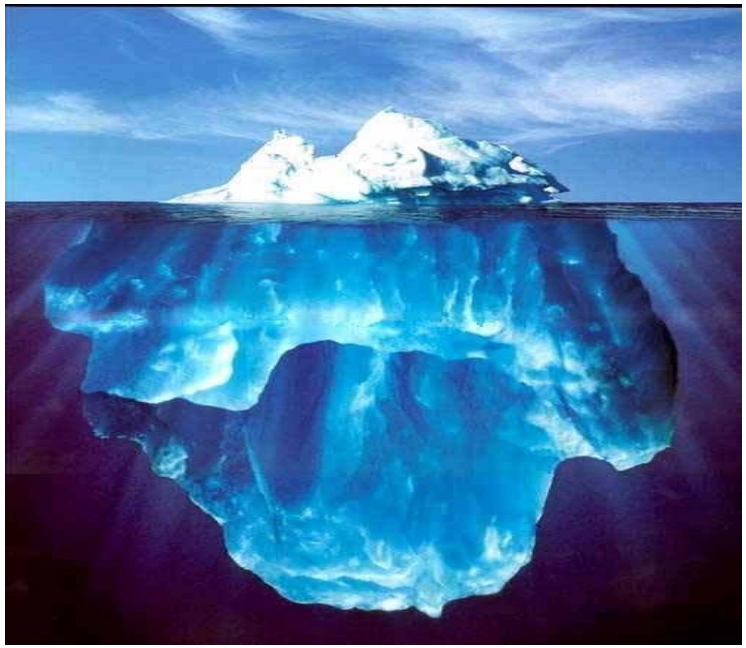
Clinical Grants and Contract Branch (CGCB)

- Manage CTEP's portfolio of clinical grants, contracts and cooperative agreements
- Provide support and assistance to grantees
- Assist in management and development of CTEP research and support contract and Cooperative Groups clinical trials




Associate Director
Dr. Meg Mooney (Acting)
Secretary to the Associate Director
Ms. Mary Louden
Administrative Office
Ms. Jackie Robinson
Nurse Consultant
Ms. Ann Setser
Protocol & Information Office
Mr. Steve Friedman (Acting)
Informatician
Mr. George Redmond
Clinical Grants & Contracts Branch
Dr. Roy Wu
Clinical Investigations Branch
Dr. Jeffrey Abrams
Clinical Trials & Monitoring Branch
Ms. Joan Mauer
Investigational Drug Branch
Dr. James Zwiebel
Pharmaceutical Management Branch
Mr. Charles "Skip" Hall
Regulatory Affairs Branch
Dr. Jan Casadei (Acting)

Interacting with the PIO

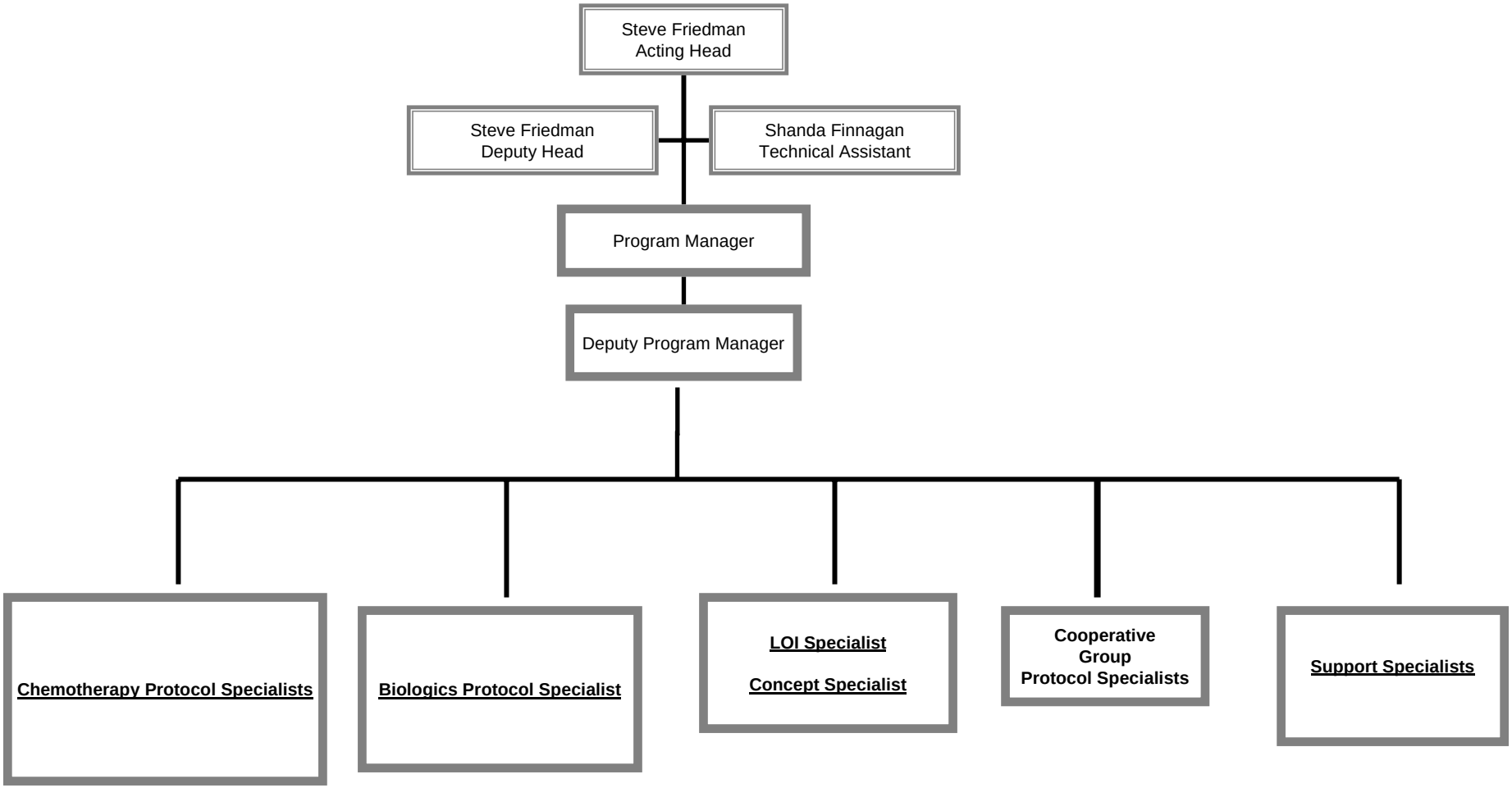


The NCI CTEP Protocol and Information Office (PIO) relieves the administrative burden related to clinical trial development and management of CTEP Staff and the extramural community.

PIO's Responsibilities

- Abstract keywords and milestones into the Enterprise system
- Prepare for and support weekly review of meetings (IDB and PRC)
- Prepares and submits weekly to FDA
- Maintain all of CTEP's study documents
- Development of 'Codes' Used for Data Submission
- Notifications/Mailings

PIO Organization Chart



Typical PIO Workload

- Approximately 1500+ ongoing CTEP-sponsored studies
- Average # of documents received per month: 200

NCI's First Performance Based Contract (2002)

The purpose of the **Government and Results Act of 1993** (GPRA or the Results Act) is to hold agencies accountable for program performance by requiring that they think strategically and set, measure and report on goals annually.

Performance Measures

- Data Abstraction/Processing of all documents submitted to CTEP PIO - Quality & Timeliness
- Electronic Storage - Quality
- Scientific Writing Support - Quality & Timeliness
- Training - Quantity and Quality
- Protocol Coding - Quality & Timeliness
- Overall Quality - Internal & External
- Support for CTEP Mailing – Timeliness
- Cost Control

How to Contact the PIO

PIO @ CTEP. NCI.NIH.GOV

(In GAL? NCI CTEP PIO w/contractors)

Phone: 301-496-1367

Fax: 301-496-9384