

**National Cancer Institute
Center for Cancer Research
Protocol Support Office**

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Discussion Points

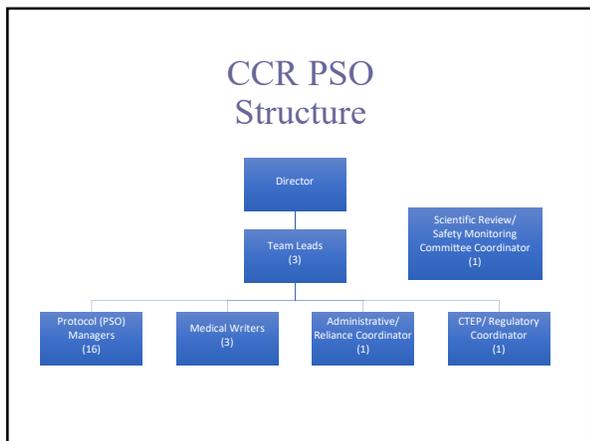
- When and why was PSO formed?
- What are the roles and who are the individuals within the PSO?
- What are the regulatory tasks that PSO manages?
- How does the PSO interact with OSRO, IRBO, and other internal/external "customers"?

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Office Origins and Changes

- Formed in late 2010/2011
- Goal to standardize/streamline regulatory operations
- Consisted of three (3) groups/teams within the "Office of Regulatory Affairs"
 PSO – IND/FDA team – NCI IRB
- Changes in 2018/2019 resulted in each of these groups becoming distinct offices
 - PSO – Protocol Support Office
 - OSRO – Office of Sponsor and Regulatory Oversight
 - NIH IRBO – NIH Institutional Review Board Office

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Protocol Support Services

- “Protocol navigation”
- Regulatory coordination through the lifecycle of the protocol
 - Protocol writing
 - Consent writing
 - Genomic data sharing determinations
 - Regulatory coordination for multi-center studies
 - Interface with pharmaceutical collaborators
 - Maintain investigator regulatory files
- CTEP investigator communication

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Submission Types

- CCR committees
 - SRC (*Scientific Review Committee*)
 - SMC (*Safety Monitoring Committee*)
 - GDS (*Genomic Data Sharing*)
- Ancillary review/safety committees
 - IBC (*Institutional Biosafety Committee*)
 - RSC (*Radiation Safety Committee*)
- IRB (*Institutional Review Board*)
 - Human subjects research studies
 - Exemption submissions
- OHSRP (*Office of Human Subjects Research Protections*)
 - Reliance agreement requests

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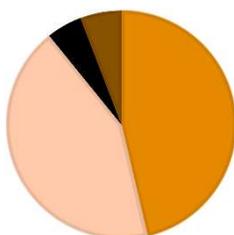
Writing Services

- Assist with writing and formatting the protocol and consent
 - Including "Supplement" for externally-sponsored/written studies
- Review protocol and consent for internal consistency, regulatory and human subjects protection language
- Initiate/draft amendment memos, and protocol and consent changes

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Workload and Resources

PROTOCOL ACTIONS
■ Amendments ■ Continuing Reviews ■ Initial Review ■ Study Closure



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Regulatory Coordination

- Develop SOPs for internal use
- Develop SOPs for CCR use
- Provide standardized training to PSO staff
- Maintain central file of regulatory documents

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Collaborative Coordination

- Pharmaceutical companies
 - Facilitate protocol/amendment review
 - Provide IRB approvals/documentation
- CTEP
 - RCR (Registration and Credential Repository) coordination
 - IAM (Identity and Access Management) account management
- Provide cursory review of Tech Transfer agreements (e.g., CTAs, CRADAs)

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OSRO Communication

- IND/IDE Communication
 - Facilitate OSRO determination/input on all initial protocols and amendments
 - Format and prepare all initial protocols and amendments for FDA submission by OSRO
- Pharmacovigilance
 - Save and maintain copies of all INDSRs, SAEs, and other safety reports/notifications in the investigator regulatory files

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SRC/SMC Board Administration

- Responsible for management, administration, and coordination of Scientific Review Committee (SMC) and Safety Monitoring Committee (SMC) meetings
- Write the minutes for SRC and SMC meetings

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Common Questions/Clarifications

- Training and training oversight/requirements
- Determination of reportable events
- Interactions and updates from OSRO and IRBO

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Questions?

Thank you!

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