Protocol Development

Erin Schubert
Administrative Director, PET Center
Protocol Development

- Idea → Grant → Protocol
- Start planning your protocol from the beginning
- Many sections of the protocol will overlap with required grant sections
- IRB submission and review can take 6-8 weeks from submission to approval
- IND submission can take additional time
Plan Your Grant

- Planning for the human subjects protocol early will aid in grant preparation
  - Helps motivate grant aims
  - Developing a budget and budget justifications
  - Evaluating necessary staff and co-investigators requiring funding
  - Human subject protections write up
Strategic Planning

- NIH grants often require IRB approval as part of JIT submissions
- Avoid delays in study start up once you receive funding
- Institutional opportunities may exist to start collecting pilot data prior to notice of award
- Multiple UPenn regulatory committees (IRB, RRSC, CTSRMC)
Protocol Building Blocks

- Background and Scientific Rationale
  - What is the purpose of the proposed research? What is the value added?

- Objectives
  - What do you hope to learn from the proposed research?

- Study Design
  - What is your plan for meeting the study objectives?
Protocol Building Blocks

- Participant selection
  - What subject population do you plan to study?

- Recruitment
  - How will you get access to your subject population? Does this require additional collaborators?

- Investigational agent?
  - Does the study require an IND?
Protocol Building Blocks

- **Procedures**
  - What research procedures will the study include? Who will perform the procedures?

- **Risks**

- **Statistical Plan**
  - How will you analyze your study results?
IND Considerations

- Does your study involve an investigational drug?
- Is the drug currently made at Penn or does it need to be developed?
- Will your study require a new IND or does Penn already have an active IND?
IND Building Blocks

- Background and Investigational Plan
- Pharmacology and Toxicology
- Previous Human Experience
- Biodistribution and Dosimetry
- Chemistry, Manufacturing and Controls
- Protocol and Investigator Information
Research Resources

Kathleen Thomas

Director, Research Operations
Department Resources

- Protocol Development Funding (Prodev)
  - Applications are reviewed quarterly (March, June, September, December)
  - Purpose: to provide financial and personnel support to Investigators to collect pilot data for grant submissions
Research Coordinator Support

- Fee for service offered through the Clinical Imaging Core (CIC) service center
  - Study start-up activities (IRB submission, budget prep, etc...)
  - Patient/Study participant management
  - Data management
  - Regulatory management
  - Billing review
  - Monitoring
Key Contacts for Protocol/IND

- Erin Schubert – Protocol, IND, Regulatory document development and submission
- Kathleen Thomas and Patty Atkinson - Radiology IND support office, handles all IND submissions and monitoring
- Sharon Lee – Cyclotron contact for development of drug synthesis, validation testing and CMC creation
Key Links - Research at Penn

- **IRB**: [https://hsera.apps.upenn.edu](https://hsera.apps.upenn.edu)
- **RRSC**: [https://ehrs.upenn.edu/radiation-safety/topics/research](https://ehrs.upenn.edu/radiation-safety/topics/research)
- **CTSRMC**: [http://www.ctsrmc.org/](http://www.ctsrmc.org/)
- **CAMRIS**: [https://www.med.upenn.edu/camris/](https://www.med.upenn.edu/camris/)
- **OCR**: [https://www.med.upenn.edu/ocr/](https://www.med.upenn.edu/ocr/)
Key Links - Research at Penn

- PennERA: 
  https://www.pennera.upenn.edu/

- RSNA grants: 
  https://www.rsna.org/en/research/funding-opportunities/research-grants
People in department

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