Nuts and Bolts of Study Start-up Timelines and Feasibility

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Study Start-up

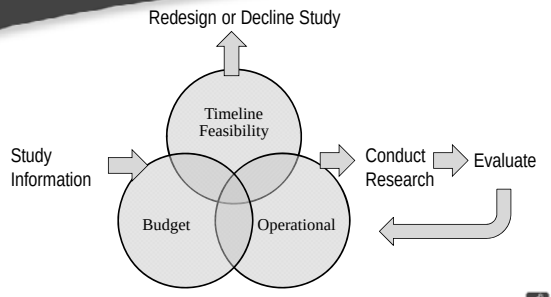
- Feasibility
  - Feasibility Analysis
- Start-up Process Timelines
  - IRB application process
  - Ancillary Review Committees

Feasibility

- Feasibility
  - 31% of the studies submitted to the IRB terminate with 1 or 0 subjects enrolled
  - $1Million cost to institution annually
  - Underperforming studies slow down the entire research enterprise at OHSU
  - Under enrollment increases the risk of bad science

Kitterman, D.R., Cheng, S.K., Dilts, D.M. & Orwoll, E.S. (2011) The Prevalence and Economic Impact of Low-Enrolling Clinical Studies at an Academic Medical Center. Academic Medicine, Vol 86(11) pp. 1-7

Protocol Analysis



Feasibility Analysis Questions

- Operational Analysis
  - Who, what, where, when, why, how
  - Do you have the required equipment? Can you use it?
  - Does the current OHSU standard of care match the protocol requirements – if not, who will pay?
  - Do we do the required tests here?
  - Do personnel have the appropriate training?
  - Space

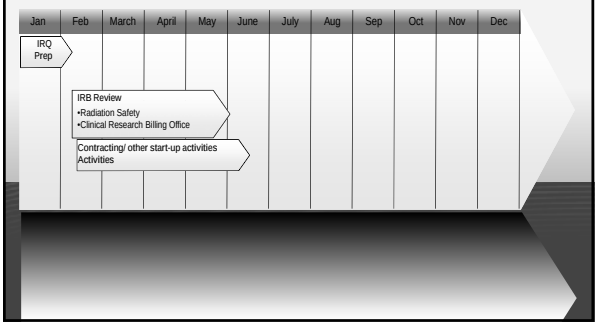
Feasibility Analysis Questions

- Budget Analysis
  - Can you complete the protocol requirements with the money you have/sponsor is willing to pay?
  - Don't guess
    - Research rates database/eCRIS
    - Personnel time (use reasonable salaries and time estimates)
    - Talk to the departments involved (send them your protocol)
    - Verify appropriate F&A rates

Feasibility Analysis Questions

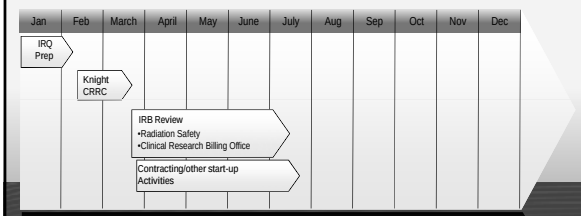
- Timeline Analysis
  - Do you have time to conduct the study and supervise staff ?
    - Bad idea to take on a study if the PI/Key personnel are leaving the institution
  - Do you have time to enroll # of subjects?
  - Average 4 months from IRB submission to contract execution and account set up
    - Say no if enrollment is expected to close within 8 months

TIMELINE PROJECT PLANNING



TIMELINE PROJECT PLANNING

Knight Cancer Institute



Timeline

- Add Time for Knight Cancer Institute Review
- Add time for additional IRB reviews (make sure you know about deadlines)
  - Deadline for VA IRB application is 2nd Monday of each month
- IND/IDE – add time for FDA review
  - 30 days can be done in parallel to IRB review
- Device Trials – add time for Medicare approval after final IRB approval

How to save time

- Have a well written final protocol
  - Grants generally don't have all the information the IRB needs
  - IRB has protocol templates and guidelines on their website
- Make sure your staff/co-Is have completed their required trainings and disclosures in Big Brain (RCR, Coir)
- Have a recruitment plan
  - Need to be able to provide the IRB with details about how you will find subjects, approach them, and what information you may need about them before consent
- Have someone with experience prepare your IRB application and/or educate yourself

Are your documents ready for IRB review?

- Did you use the right templates?
- Do all of your study documents match?
  - Consent risks and procedures match protocol
  - Data and safety monitoring plan is adequate and manageable
  - Initial Review Questionnaire (IRQ) matches the other study documents
- Did you upload all of the required documents?
  - Appropriate consents and HIPAA authorization forms
  - Preparatory to Research Forms/ Waiver of Authorization
  - Advertisements, telephone screening scripts, recruitment letters
  - Knight Documents (if study involves cancer)

After IRB approval (but before you can start)

- Contract finalized
- Sponsored Project Administration – OGA Project # assigned
- Patient Billing Services (PBS) – industrial account set up if necessary
  - need to have secured research rates
- Now done in eCRIS if the study is prospectively consenting subjects