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

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


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

- 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

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)

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
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