REQUIREMENTS FOR PRINCIPLE INVESTIGATORS
Design and implementation of a core curriculum
Development of Investigator manuals

Core Content topics

1. Overview of the Drug Development process
   - Description of the Phases and the regulatory requirements of each

2. Study design and Protocol development (the basics based on intended outcome)
   - Bioequivalence
   - First time in man - dose determination
   - Ascending dose tolerance studies
   - CYP450 subset phenotyping
   - Drug Interaction studies
   - When to use Crossover studies
   - Importance of Blinding

3. Review of Statistical methods including:
   - The determination of power and sample size
   - Overview of statistical study designs

4. Study conduct issues - how studies are done
   - What is GCP and how it is applied
   - Subject/Patient safety assurances
   - Reporting of AE’s and SAE’s

5. Making Protocols conform to the ICH guidelines:
   - The ICH guidelines important to the PI.

6. Review of Pharmacokinetic issues including
   - AUC, Tmax, Cmax, etc
   - Half life and how to use it

7. How to approach studies in special populations (compromised hosts)
   - Renal impaired subjects
   - Hepatic impaired subjects
   - Diabetes - special problems
   - Asthma - special problems
   - Hypertension, etc

8. The IRB process and the expected relationship of the PI to the IRB

9. The Informed Consent - what is required

10. Ethical issues faced by Physicians in Clinical research

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