What are SOPs?

- Standard = Routine
- Operating = Working
- Procedures = Methods
- Serves as Regulatory “Memory”
- Serves as Corporate “Memory”

What does the SOP say!!!!!!!

What are SOPs NOT?

- Something to put on a shelf
- Something only used to show regulators or Sponsors
- Something written to avoid deviations
- Something to buy or have a consultant write

“A testing facility shall have standard operating procedures in writing setting forth study methods that management is satisfied are adequate to insure the quality and integrity of the data generated in the course of a study.”
Standard Operating Procedures

Purpose
- Consistency between scientists and procedures
- Standardizes terminologies
- Adjunct to protocol
- Reconstruct prior facility practices
- Make all facility procedures visible
- Provides study personnel with written instructions
- Allows management to assure correct scientific practice

Benefits
- Serves as guidelines in training new staff
- Reduces time spent documenting routine procedures
- Minimizes errors/repeats
- Standardizes data recording and reporting
- Perpetuates scientific expertise and experience learned through the school of hard knocks
- Helps tie requirements of various regulations into single user friendly documents
- Justifies a company’s position on certain issues