Inservice Guidelines

Please bring the following information:

- Copies of flowsheets for nursing documentation
- Copies of MD orders
- Initial IRB approval, if not already provided, and any updated or revised regulatory documents
- Oracle string, if not already provided
- Processing instructions
- Bionutrition orders

Below is an outline of the information to present during your protocol inservice:

I. Protocol title

II. Phase I, II or III (or variation thereof, Phase I/IIa)

III. Name of Principal Investigator

IV. Brief overview of study
   - Include the aims/goals of the study
   - Length of study
   - Number of participants you plan to enroll
   - Length of time participant is involved in the study
   - Review information about the study drug; dosage, administration, side effects, premeds, MD notifications, criteria for withholding drug
   - Anticipated start up date

V. Discuss in detail the assistance needed from the CRU
   - Frequency and length of study visits
   - Nursing tasks, drug administration, PK, PD, PG collection, proper handling of specimens (invert tube and place immediately on ice) ECG, RMR, glucose tolerance testing
   - Will the participant need to leave the unit for other testing during the study visit? If yes, location and frequency of testing.
   - Data recording (bring copy of flowsheets)
     - What information do you need recorded? (e.g., vital signs, height, weight, infusion start/stop time, PK, PD, PG collection times)

VI. Discuss Bionutrition needs in detail
   - Bionutrition assistance, special diets
   - Anthropometrics
   - Food records or dietary recalls

VII. Provide lab with copy of Lab Manual and discuss in detail processing instructions for protocol samples collected
   - Type and number of collection tubes
   - Are the collection tubes and labels being supplied by the study?
   - Are samples ambient, refrigerated, or frozen?
   - Centrifuged at what speed for how long?
   - Storage in refrigerator, -20 or -80 freezer?
   - Number of aliquots, time points, and labeling instructions
   - Any additives to tubes?