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?