Ready, Set, Go

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Study Activation

- Site selected
- Consents created
- IRB approved
- Now what......
Get Prepared

You need to gather the key stakeholders for success of your study implementation…Do you know who they are?
Examples of requirements for CRC Activation

- PI
- Study Coordinator
- Research Pharmacist
- Nursing CRC
- Bio-nutrition
- RSA
- Lab tech
Everyone Participates

All CRC staff members involved in the conduct of the study will be participating in this meeting. To assist you with the preparation for this meeting, we have prepared an outline of points you will need to address depending on the complexity of your research project.
Introduction

- History (about 5 minutes)
- Science (about 5 minutes)
- Patient Schedule
Important Info to provide

- Number of patients to be studied
- Visit or admission schedule
- Number of visits or admissions per patient
- If necessary, special day or time requirements
- Facilities required (i.e. treatment room, infusion room, etc.)
- Length of stay
Items to Discuss with team

- Principal Investigator/Fellow Responsibilities
- Nursing/Coordinator
- Bionutrition Research Responsibilities
- Equipment/Supplies
- Drugs/Biologicals
- Role of the research pharmacist
More Discussion

Storage

Short term please specify how often specimens will be shipped ____________

Long term please specify length ______________
Your Specimens- very important

- Specimens
- Collection
- Person responsible
- Special containers
- Processing Instructions (please provide in writing if not included in the protocol)
- Destination (note person responsible and contact information)
- Shipping instruction
Medical Orders

- This is a hospital....
- If it is not written, it is not done
- Be clear, concise and specific especially if working with medical staff (nurses, doctors, etc that are not involved in research everyday)
At the end of the day

- You have information
- Share it so that everyone is on the same page
- Write it down so that everyone knows what you need to collect
- This will help prevent unwanted queries from sponsors
- Update and disseminate new information gained
Guideline

This guideline will be available on the intranet as a tool to assist. It has gone thru many changes over the years and can be tailored to fit your study team needs outside the CRC…

Questions???????