

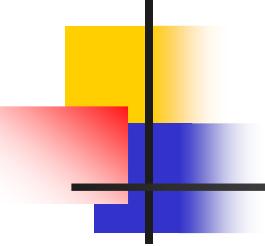


**Lynn Spear, Financial Manager,
Duke Comprehensive Cancer Center**



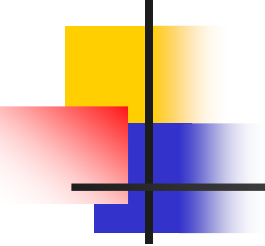
Topics of Discussion

- Radiology and Clinical Trial Budgets
- Sample Justification Budgets
- Incorporating Radiology Cost



Clinical Trial Budgets and Radiology

- What Does a Sponsor want to see in a Clinical Trial Budget with Radiology Scans?
 - Complete breakdown of by visit or cycle, how many? Can any scans be invoiced?
 - Inclusion of Technical and Professional Fees
 - Inclusion of professional readings within the radiology scan line item or separately (depends on how Institution breaks down costs).
 - Written or verbal justification for each item listed
 - Administrative or Start-up fees (complete breakdown of costs and why the need for the charge.



Clinical Trial Budgets and Radiology

- Are any 3rd party vendors involved with reviewing scans? (i.e. Radpharm? Virtualscopics?)
- Why do I need to include 3rd party vendors in my budget?
- What other people need to be included in my budget concerning Radiology scans? Study Coordinators? Radiology team members?



Sample Justification Budget

- The purpose of a justification is to provide the Sponsor a detailed account of all items and to define the projected budget amount you are requesting.
- Consider the people who are involved before a study can start. For example, Duke's Radiology department is now charging a startup fee that covers their effort to review and determine what is involved with the protocol before they begin the project. Typically, Radiology does not receive any direct compensation to work on research studies.
- Ask who and what services will be needed from your Radiology staff and make sure you can explain it back to the Sponsor business person who may have never worked in a site setting.

Incorporate Radiology Cost



- When incorporating Radiology Costs in a budget, figure how frequent your scans are going to take place. Are items priced together or individually?
- Is it feasible to do the Radiology scans at the site? (i.e. do you have the proper equipment).
- Can any Radiology items be invoiced?



Incorporate Radiology Cost

- Do you know the institutional approval process regarding incorporating costs into a budget?
- Institutional business official needs to know what kind of committee or formal approval process must take place before he/she can incorporate prices in budgets.



Incorporate Radiology Cost

- Do an Internal Cost Summary.
- Do you know the relevant CPT codes and how payments will be invoiced to your Radiology dept. or hospital?
- Will a discount rate be used?
- If a Sponsor is unable to cover all the costs will your internal dept. be able to cover the costs?



Summary

- Understand every item that you have included in your budget.
- The business official needs to be able to explain how you arrived the final budget price (know your price sources).
- Double check all numbers to ensure they add correctly (across and down).
- Make sure you all the appropriate sign-offs in your dept. before incorporating prices.