Information Provided by: Alliance Advocate Committee

Tips on Reviewing Clinical Trial Protocols
An Advocacy Approach

Protocol Review Steps

1. Review informed consent form first, then protocol
2. Identify problems with protocol
    - Focus in what this would do for the patient & what a person would have to do
    - Write them down, w/suggested changes if possible

Points to consider during review

- Patient burdens
- Risk
- Trade-offs
- What's different that standard treatment?
- What are they looking for in the trial (objectives & endpoints)?
- How is it (might it be) better than what exists?
- What is the clinical significance?
- What is the clinical significance? In absolute and relative terms.
- Are there ways to tie in QOL, correlative science, other patient considerations?

Study design

- What will patients consider or shy away from?
- Is standard of care changing so this study would be irrelevant? To doctors? To patients?
- What's the competition for this trial? For the patient population? Within institutions? Industry trials?
- What else can we learn in this trial with this group of people?
- Do we need a control arm and what is the appropriate control? Historical control?
- Does it have to be randomized? If so, why?
- Correlative science component (tissue collection and testing)?
- Survey of life assessment component?
- Immunology Component?

Eligibility Criteria

- Are they necessary for the trial?
- Is this reasonable? Are they too restrictive? Not restrictive enough?
- What about other health problems (for example, diabetes)? Could some be eligible?
- Life expectancy criterion - what is it based on? Is this really necessary?

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Background Reading

Clinical Trial Information

- Read "Cancer Clinical trials: Experimental Treatments and How They Can Help You" by Robert Finn; O'Reilly publishing
- Go to http://cme.cancer.gov/clinicaltrials/learning/incorporating-clinicaltrials.asp and take the course on 'Incorporating Cancer Clinical Trials Into Your Practice' for a good overview of what is involved in the clinical trial process.
- NCI website http://www.cancer.gov/clinicaltrials/findtrials to find other trials
- Clinical trial questions and others who have "questions to ask" (i.e. http://www.cancer.gov/clinicaltrials/learning)

Informed Consent:

- Go to http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp and take the online course on 'Human Participant Protections Education for Research Teams'
- NCI Simplified Informed Consent Form at http://ctep.cancer.gov/guidelines/consent.html and http://www.cancer.gov/clinicaltrials/understanding/simplification-of-informed-consent-docs
- Federal Regulations: the Common Rule at http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm
- Also information available at http://www.hhs.gov/ohrp/

Disease Information:

- Go to NCI www.cancer.gov and click on the type of cancer general information.
- www.cancer.org (American Cancer Society) also has some information under 'Choose a Cancer Type or Topic' on their home page.
- Google the specific disease to find organizations/information on that disease.