How Do I Decide About A Clinical Trial?

Christina Amidei, APN, PhD
Director of Clinical Research
Neurological Surgery
Why Participate?

• Cure is not available
• Side effects of treatment occur
• Potential benefits
  – Access to options not available to others
  – Closer observation
  – You may be the first to benefit
  – You may help others

Goal: To improve standard of care
What is a Clinical Trial?

• Structured treatment program designed to identify risks and benefits of new (experimental) treatment options as compared to the standard of care

• Standard of care is based on previous research

• Not necessarily an “either/or” comparison
Clinical Trials

• Clinical trials can test drugs

• Clinical trials can test devices

• Clinical trials can test other therapies

• Often sponsored by someone - it is important to know who is sponsoring the trial
Who Sponsors Clinical Trials?

From: The NCCN website
Phases of a Clinical Trial

It is important to know the phase of study for any clinical trial, and whether it adds to or is used instead of standard of care.
What is a Placebo?

• Substance thought to have no therapeutic effect
  – Does it really have no effect?
• Patients and researchers don’t know if you are receiving the placebo or study drug
• Helps to tell if the response is “real”
• Placebo studies ADD to the standard of care

It is important to know whether the study involves a placebo
But there are risks......

• New treatment:
  – May not work for you, even if it works for others
  – May have side effects that are worse than standard of care

• May require additional tests or visits

• Risks are spelled out in a consent form
  – Likely (expected), less likely or unexpected
  – May be difficult to distinguish from the disease
And there are rules....

• Rules of clinical trials are specified in protocols
• Generally more rigid than standard of care
• Specifies:
  – Who can participate
  – When visits are to be made
  – When tests are to be done
  – When to start and stop
What Are My Rights and Responsibilities?

Rights

• To ask questions and get answers about specific trials
• To receive usual care and be presented options other than research
• Confidentiality
• Access to medical records but no access to research records

Responsibilities

• Work with your providers as part of the team- follow rules, attend appointments
• Let them know what you are experiencing- don’t assume it is expected!
What About Costs?

• The consent includes what you will pay for and what is paid for by a research fund.

• Illinois insurance plans are required to pay for routine care within a clinical trial with some exceptions.

• There are often additional costs such as transportation, parking, etc. that may not be covered in a research study.
Other Important Considerations

• Only **you** can decide about participation in a clinical trial
• Read the consent!
  – Have others read it as well
• You can stop a clinical trial at any time
• Ask about clinical trials, don’t wait for someone to offer it to you
How can I learn about clinical trials?

- Ask your providers
- Do your own research
- Look at your treating facility website
Explore These Resources

- http://clinicaltrials.gov/
- http://cancer.northwestern.edu/clinicaltrials/DS162_Brain%2C%20nervous%system