

# **How to Help Write a Good Consent Form: MOVING FROM INFORMED CONSENT to INFORMED CHOICE**

**Peggy Devine**  
Founder & President  
Cancer Information & Support Network (CISN)

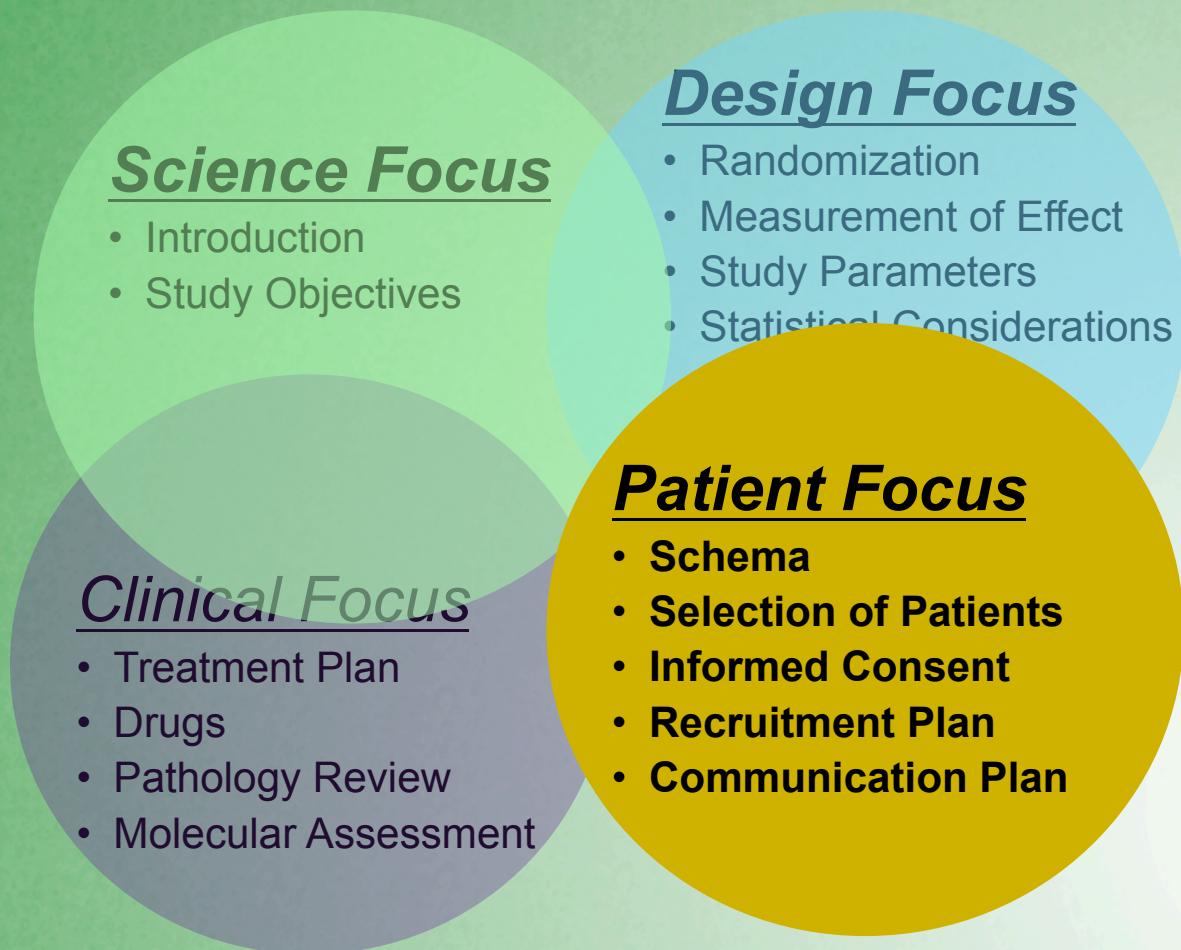
C3 ASCO advocate training  
January 19, 2007

---

*A Grassroots Organization Providing Awareness & Action*



# FOCUSING on the PATIENT



A Grassroots Organization Providing Awareness & Action



# OBJECTIVES

- Learn what constitutes a good consent
  - **Make recommendations to improve the .. consent form**
- Learn what constitutes a good accrual plan
  - **Make recommendations for .....**
- Learn what constitutes a good communication plan
  - **Make recommendations for .....**

---

A Grassroots Organization Providing Awareness & Action



# APPROACH

- **Background**
  - What the process looks like today
- **Why we need to be involved**
- **Learn to review and construct a good consent form**
  - Use both .... and IMPACT form
    - Content
    - Format
    - Additional materials
- **Today: focus on the form (always use the NCI 2004 template)**
- **Will discuss a good accrual & communication plan**
  - Make recommendations

---

A Grassroots Organization Providing Awareness & Action



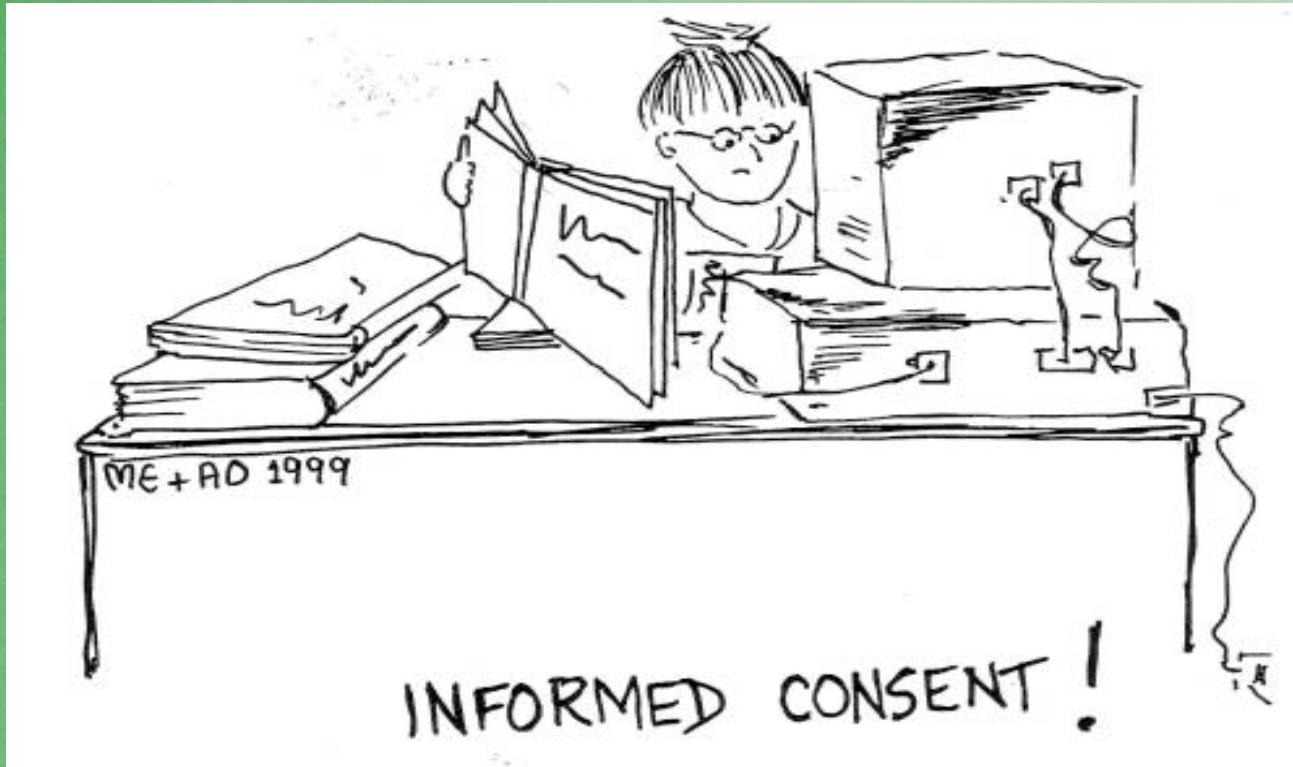
# **What 5 Things Would Patients Need to Know About Study Before Enrolling**

- We will re ask this at the end of this section
  - Write down your thoughts as we go

*A Grassroots Organization Providing Awareness & Action*



# This Is Not What You Want



A Grassroots Organization Providing Awareness & Action



# ALL PATIENTS ARE THE SAME



- They have just received devastating health information.
- Cancer has been diagnosed or recurred.

A Grassroots Organization Providing Awareness & Action



# EACH PATIENT IS UNIQUE



- Learning Style
- Age
- Ethnicity
- Family
- Career
- Values
- Other

A Grassroots Organization Providing Awareness & Action



# The Informed Consent Process

- **Mandatory Process**

- Focus is on the consent form not on the process
  - Developed by committee with focus on liability and research needs
  - Does “human subject protection” guarantee “human subject” comprehension?

- **Reality in the research trenches**

- Form development delegated to staff with minimal infrastructure and funding
- Medical professionals have little training, few patient ed materials and little time

- **Patient Perspective**

- Cancer diagnosis = patient overload
- IC is patient's only knowledge of the trial

A Grassroots Organization Providing Awareness & Action





Patient Diagnosed: Shock & Fear

Very Complicated Legal Form

Few Graphic Handouts

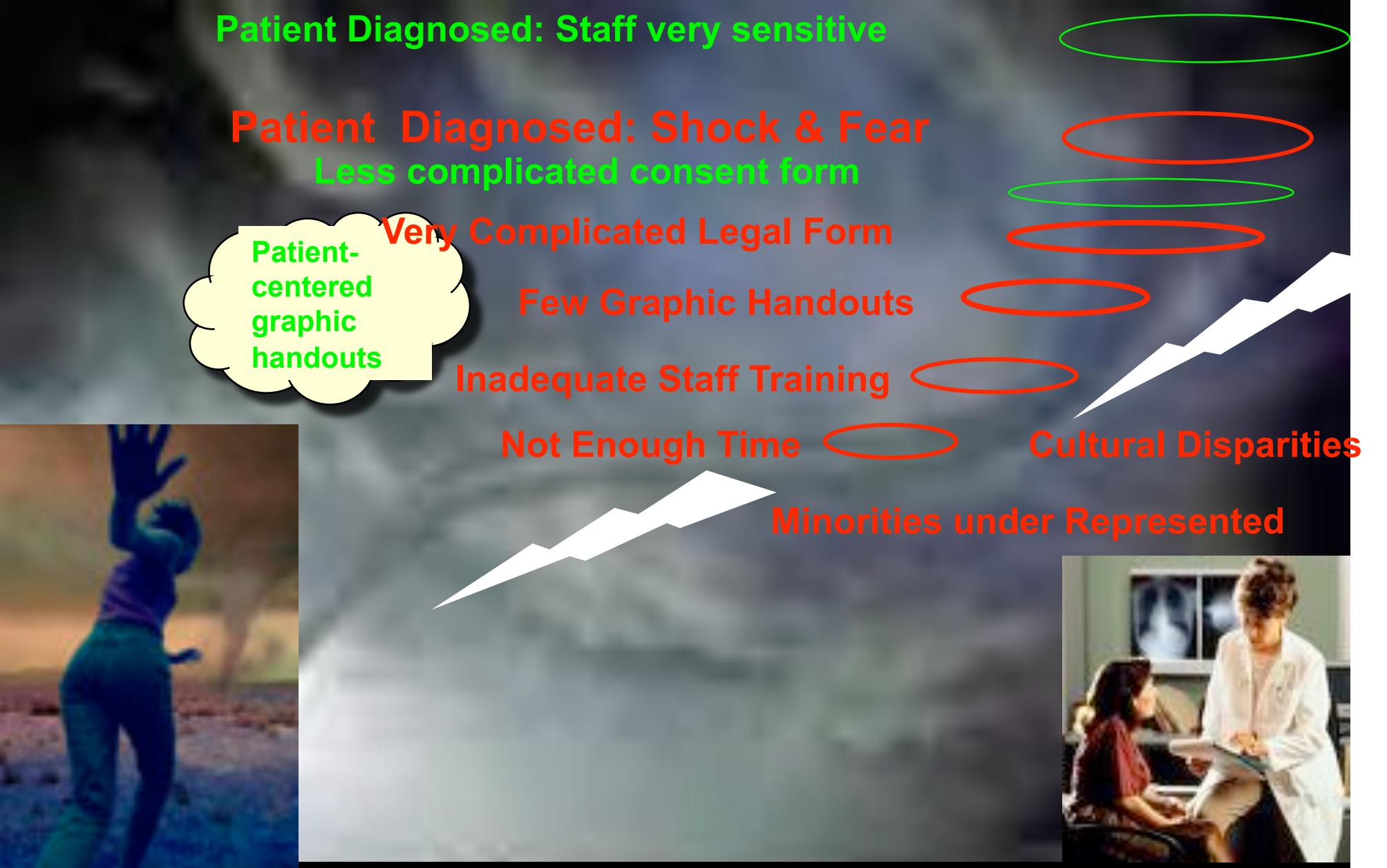
Inadequate Staff Training

Not Enough Time

Cultural Disparities

Minorities Under Represented

The **PERFECT STORM**



Patient Diagnosed: Staff very sensitive

Patient Diagnosed: Shock & Fear  
Less complicated consent form

Patient-centered  
graphic  
handouts

Very Complicated Legal Form

Few Graphic Handouts

Inadequate Staff Training

Not Enough Time

Cultural Disparities

Minorities under Represented



An **INTERACTIVE**  
**INFORMED CHOICE PROCESS**

# Where Do Advocates Come In?



**Researchers** (bench)



**Advocates can be the bridge  
For all translational research**

**Patients** (bedside)



*A Grassroots Organization Providing Awareness & Action*



# Collaboration is Always Better



A Grassroots Organization Providing Awareness & Action



# Problems With Consent Documents

- Used as legal & not educational tool
- Too long and too complicated
- Reading level too high
- Not geared to minority concerns
- Lack of summary page, schemas, tables, calendars and graphics

Slide courtesy of Ralph Kennedy

A Grassroots Organization Providing Awareness & Action



# What Constitutes a Good Consent Form

- Ethical disclosure
- Tells patient what the study is about
- Tells patient what standard of care is
- Makes all study requirements clear ( calendar flow-chart )
- Makes all risks for standard vs study clear ( Table )
- Reading level at 6th grade
- Formatted correctly
- Understandable

A Grassroots Organization Providing Awareness & Action



# What Constitutes a Good Consent Form

- Ethical disclosure
  - Explains this is a research study
  - Patient can:
    - drop out,
    - discuss with your family,
    - take your time
  - Informs patient about:
    - costs,
    - confidentiality,
    - injury,
    - other choices

---

A Grassroots Organization Providing Awareness & Action



# IS There Ethical Disclosure in this study?

- Yes – all information has been disclosed BUT not all information is clear
- We do not know anything about the process from reading the form

A Grassroots Organization Providing Awareness & Action



# What Constitutes a Good Consent Form

- Ethical disclosure
  - Explains this is a research study
  - You can drop out, discuss with your family, take your time
  - Costs, confidentiality, injury, other choices
- Tells patient what the study is about
- Tells patient what standard of care is
- Makes all study requirements clear ( calendar flow-chart )
- Makes all risks for standard vs. Study clear ( Table )
- Reading level at 6th grade
- Formatted correctly
- Understandable

A Grassroots Organization Providing Awareness & Action



# Does this study clearly tell the patient what the study is about?

## In the protocol

- Background and justification  
Hypothesis: hard to dig out
- For Chemo - page 9-10
- For markers – page 5,9-10

## In the consent form

- Yes but is it clear?
- For Chemo – Pg 61
- Markers – pg 61

A Grassroots Organization Providing Awareness & Action



# What Constitutes a Good Consent Form

- **Ethical disclosure**
  - Explains this is a research study
  - You can drop out, discuss with your family, take your time
  - Costs, confidentiality, injury, other choices
- **Tells patient what the study is about**
- **Tells patient what standard of care is**
- **Makes all study requirements clear** ( calendar flow-chart )
- **Makes all risks for standard vs study clear** ( Table )
- **Reading level at 6th grade**
- **Formatted correctly**
- **Understandable**

A Grassroots Organization Providing Awareness & Action

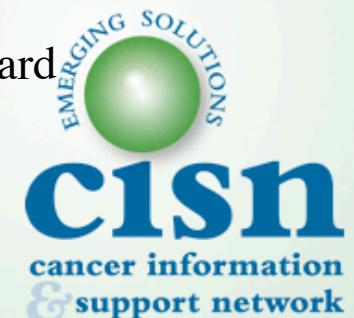


# Does this Study Tell the Patient What Standard of Care Is?

- **In the protocol:**
  - Observation remains an appropriate option
- **In the consent form:**
  - **In the side effects / risk section**
    - Currently, the standard of care is to receive no chemo
  - **What other options are there?**
    - Choose not to be in study
    - Enter a different study
    - Get no (**further**) treatment – do not mention this is standard of care

**Break into groups – rewrite this**

A Grassroots Organization Providing Awareness & Action



# What Constitutes a Good Consent Form

- **Ethical disclosure**
  - Explains this is a research study
  - You can drop out, discuss with your family, take your time
  - Costs, confidentiality, injury, other choices
- **Tells patient what the study is about**
- **Tells patient what standard of care is**
- **Makes all study requirements clear** (calendar flow-chart)
- **Makes all risks for standard vs study clear** (Table )
- **Reading level at 6th grade**
- **Formatted correctly**
- **Understandable**

A Grassroots Organization Providing Awareness & Action



# Does this Study Make all Study Requirements Clear?

**Schema  
removed due to  
confidentiality**

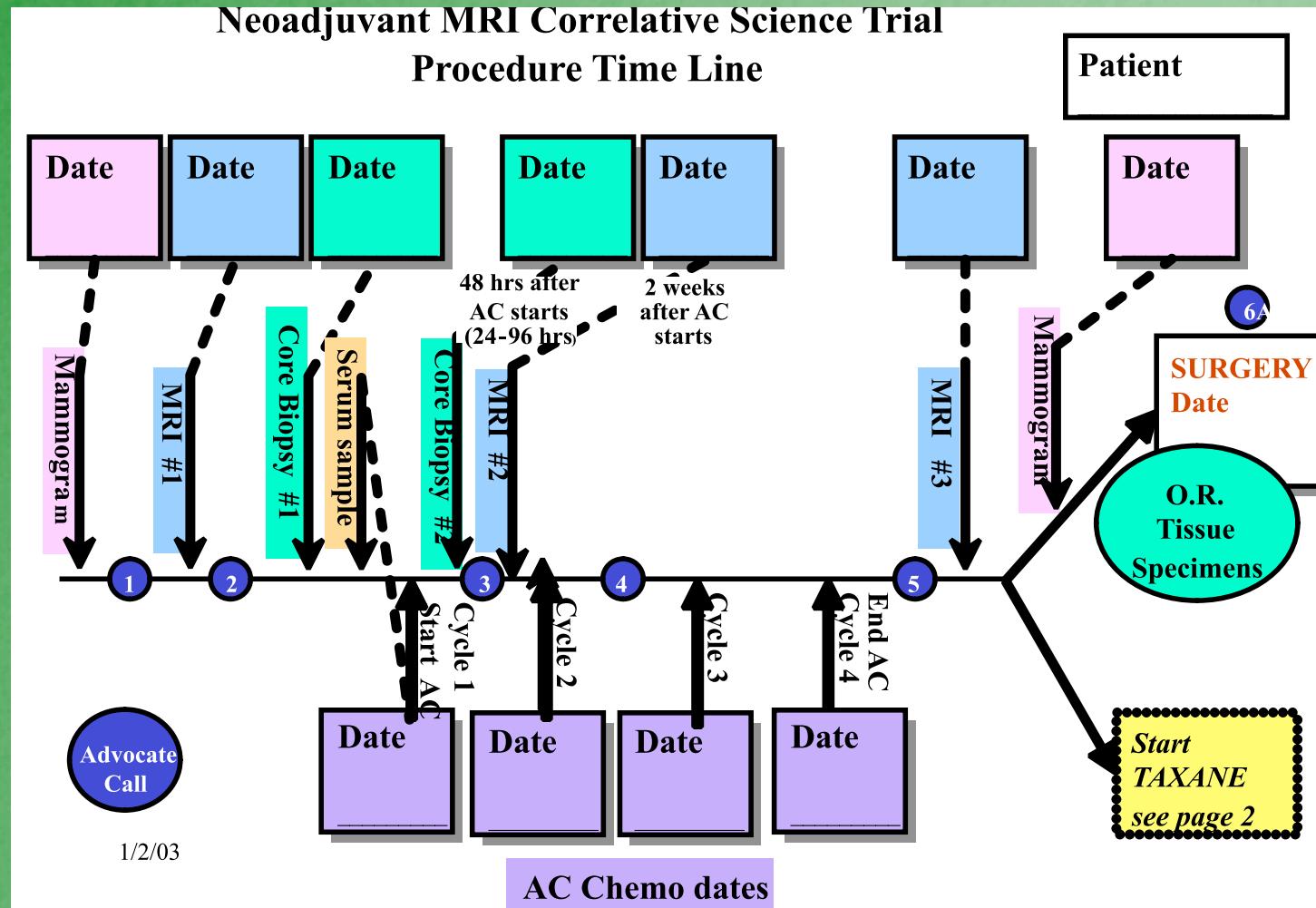
- What can you learn from the schema?
  - You will be randomized by marker results
  - Chemo names
  - Chemo schedule
- What is not clear?
  - How this translates to your life

## Recommendations?

A Grassroots Organization Providing Awareness & Action



# Example of a patient centered study schema

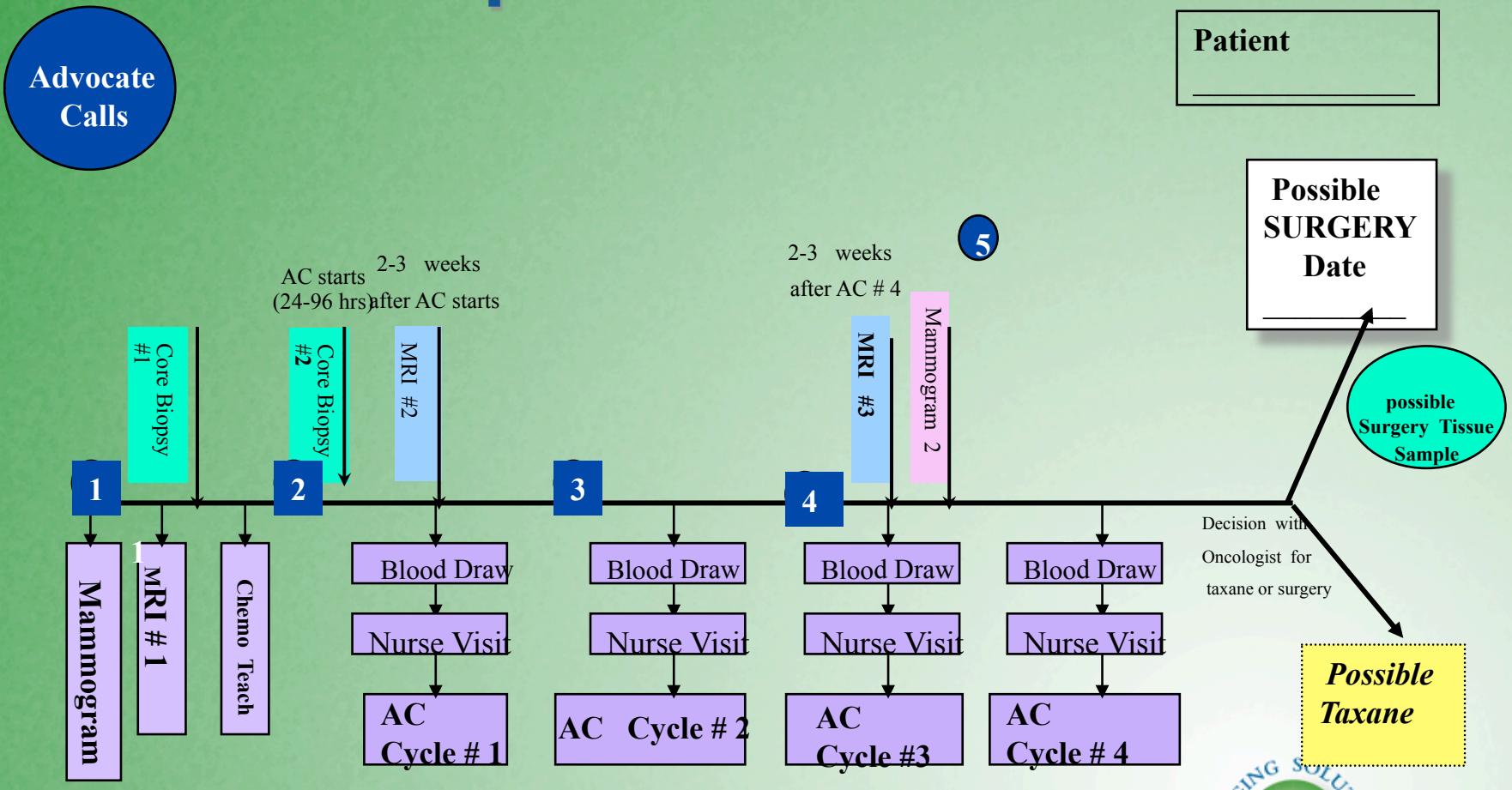


Study timeline developed by Peggy Devine

A Grassroots Organization Providing Awareness & Action



# Example # 2 of schema



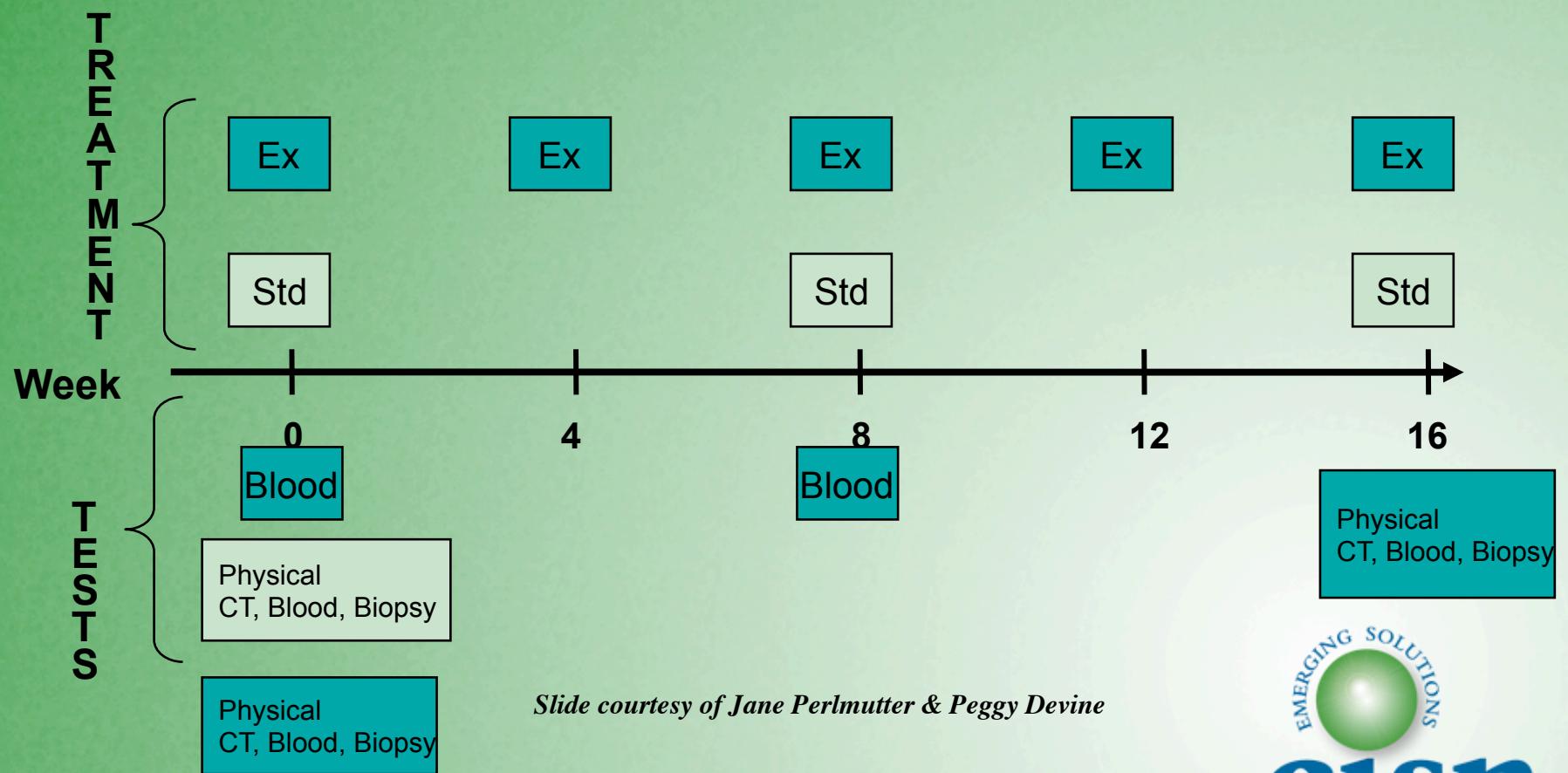
**STANDARD TREATMENT :** you are responsible for making all appointments

*Study timeline developed by Peggy Devine*

A Grassroots Organization Providing Awareness & Action

**c1sn**  
cancer information  
& support network

# Example: Phase 3 Patient Schedule



*Slide courtesy of Jane Perlmutter & Peggy Devine*

A Grassroots Organization Providing Awareness & Action



# What Constitutes a Good Consent Form

- **Ethical disclosure**
    - Explains this is a research study
    - You can drop out, discuss with your family, take your time
    - Costs, confidentiality, injury, other choices
  - **Tells patient what the study is about**
  - **Tells patient what standard of care is**
  - **Makes all study requirements clear** ( calendar flow-chart )
  - **Makes all risks for standard vs. study clear** ( Table )
- 
- **Reading level at 6th grade**
  - **Formatted correctly**
  - **Understandable**

A Grassroots Organization Providing Awareness & Action



# Does this Study Make all Risks and Side Effects Clear?

## What do you know?

- Side effects of all drugs
- If the hypothesis is wrong you may receive chemo when you didn't need it

## What don't you know?

- Some long term side effects of chemo: secondary cancers, chemo brain

## Recommendations?

Break into groups to rewrite this



# Example: Presenting Side Effects

Drug or Test		Side Effects		
Name	Standard or Experimental	Common (>10% of patients)	Occasional (3-9% of patients)	Rare (<2% of patients)
Drug x	Experimental	<ul style="list-style-type: none"> <li>• rash</li> <li>• fatigue</li> </ul>	<ul style="list-style-type: none"> <li>• <i>anemia</i></li> <li>• <i>nausea</i></li> </ul>	<ul style="list-style-type: none"> <li>• <b>infection</b></li> </ul>
Drug y	Standard	<ul style="list-style-type: none"> <li>• hair loss</li> </ul>	<ul style="list-style-type: none"> <li>• <i>low white cell count</i></li> <li>• <i>vomiting</i></li> </ul>	<ul style="list-style-type: none"> <li>• <b>heart damage</b></li> <li>• <b>blood clot</b></li> </ul>
Blood Draw	Standard	<ul style="list-style-type: none"> <li>• mild pain</li> </ul>	<ul style="list-style-type: none"> <li>• bruising</li> </ul>	
Bone Marrow	Experimental	<ul style="list-style-type: none"> <li>• pain</li> </ul>	<ul style="list-style-type: none"> <li>• <b>infection</b></li> <li>• bruising</li> </ul>	<ul style="list-style-type: none"> <li>• <i>allergic reaction</i></li> <li>• <b>hitting a nerve</b></li> </ul>

**Red Bold:** indicates side effects may be permanent, serious or fatal

**Green Italic:** indicates side effects are generally resolved with additional drugs

Plain: indicates other known side effects

Slide courtesy of Peggy Devine & Jane Perlmutter

A Grassroots Organization Providing Awareness & Action



# What Constitutes a Good Consent Form

- **Ethical disclosure**
  - Explains this is a research study
  - You can drop out, discuss with your family, take your time
  - Costs, confidentiality, injury, other choices
- **Tells patient what the study is about**
- **Tells patient what standard of care is**
- **Makes all study requirements clear** (calendar flow-chart)
- **Makes all risks for standard vs study clear** ( Table )
- **Reading level at 6th grade**
- **Formatted correctly**
- **Understandable**

A Grassroots Organization Providing Awareness & Action



# Informed Consent Literacy

Generally:

- Most consent forms are written at 10-16<sup>th</sup> grade reading level.
  - Use plain English at the 6<sup>th</sup> - 8th grade level (check in MS Word or use Flesch formula)
  - Don't use jargon or acronyms
  - Use shorter sentences
  - Omit complex words (use substitution word list)
- Comprehension and recall of consent information is poor – 30% could not recall being in a research study within 10 weeks

This study

- Microsoft word test – 6<sup>th</sup> grade reading level ~
- Use word substitution list

*Slide courtesy of Ralph Kennedy*

A Grassroots Organization Providing Awareness & Action



# What Constitutes a Good Consent Form

- **Ethical disclosure**
  - Explains this is a research study
  - You can drop out, discuss with your family, take your time
  - Costs, confidentiality, injury, other choices
- **Tells patient what the study is about**
- **Tells patient what standard of care is**
- **Makes all study requirements clear** ( graphic flow-chart )
- **Makes all risks for standard vs study clear** ( Table )
- **Reading level at 6th grade**
  - **Formatted correctly**
  - **Understandable**

A Grassroots Organization Providing Awareness & Action



# Formatting The Document

## Generally

- Use font size of 12 or greater:
- Use fonts with “tails”, like GRAMMOND, CENTURY or COPPER PLATE LIGHT
- Bullet all study requirements
- Make sure all headings are bolded
- Make sure all risks are bulleted
- Use short paragraphs
- Lots of white space



Slide courtesy of Ralph Kennedy

A Grassroots Organization Providing Awareness & Action



# SUMMARY

- Consent process discussed in protocol:
- Consent form
  - Ethical disclosure :
    - Explains this is a research study
    - You can drop out, discuss with your family, take your time
    - Costs, confidentiality, injury, other choices -
  - Tells patient what the study is about:
  - Tells patient what standard of care is:
  - Makes all study requirements clear (calendar type flow-chart):
  - Makes all risks for standard vs study clear ( Table ) :
  - Reading level at 6th grade:
  - Understandable

A Grassroots Organization Providing Awareness & Action



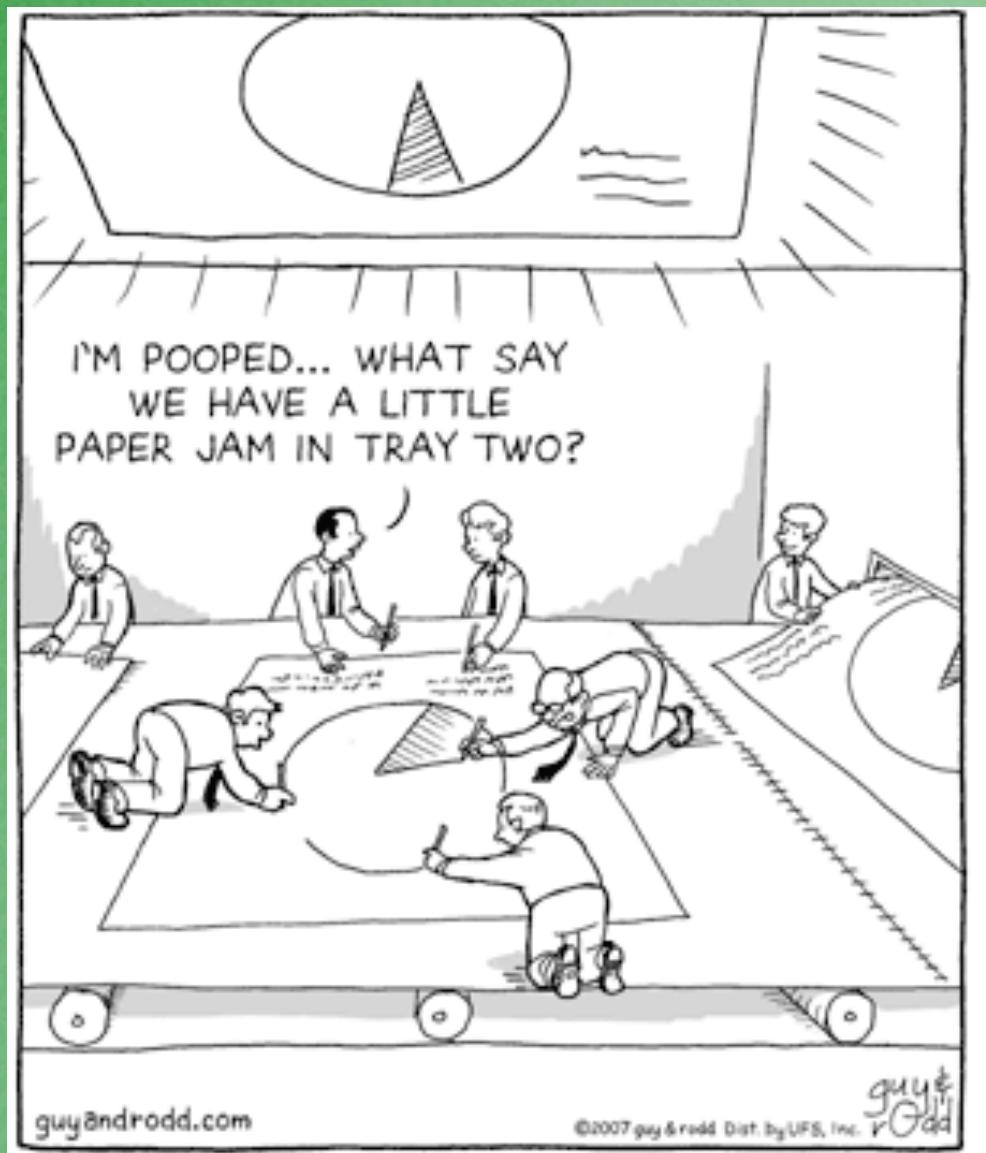
# **What 5 Things would Patients need to know about this Study before Enrolling**

- **What does this study ask me to do?**
  - If I don't want to know if I was high-risk – don't enroll
  - If I absolutely want chemo - don't enroll
  - If I absolutely don't want chemo – don't enroll
- **How does this differ from standard of care?**
- **Side effects of chemo- short and long term**
- **This is a research study – as likely to be true as not**
- **Other**

---

A Grassroots Organization Providing Awareness & Action





A Grassroots Organization Providing Awareness & Action





Stuff to do when you have cancer...

#16: Use a Nerf Ball™ to see if your oncologist has a sense of humor.

A Grassroots Organization Providing Awareness & Action



# An Effective Accrual Plan

- A Well designed study
  - A well written consent form
  - Developed before the study opens
- 
- Staff
    - Strategies to reach community doctors
    - Training: psychosocial aspects of diagnose on patient
  - Patients
    - Education materials
  - Communities
    - Community outreach
    - Strategies to reach under represented communities

A Grassroots Organization Providing Awareness & Action



# Developed before the study opens

- NO indication of this

A Grassroots Organization Providing Awareness & Action



# An Effective Accrual Plan

- Developed before the study opens
  - Staff
    - Strategies to reach community doctors
    - Training: psychosocial aspects of diagnose on patient
  - Patients
    - Education materials
  - Communities
    - Community outreach
    - Strategies to reach under represented communities

A Grassroots Organization Providing Awareness & Action



# An Effective Accrual Plan

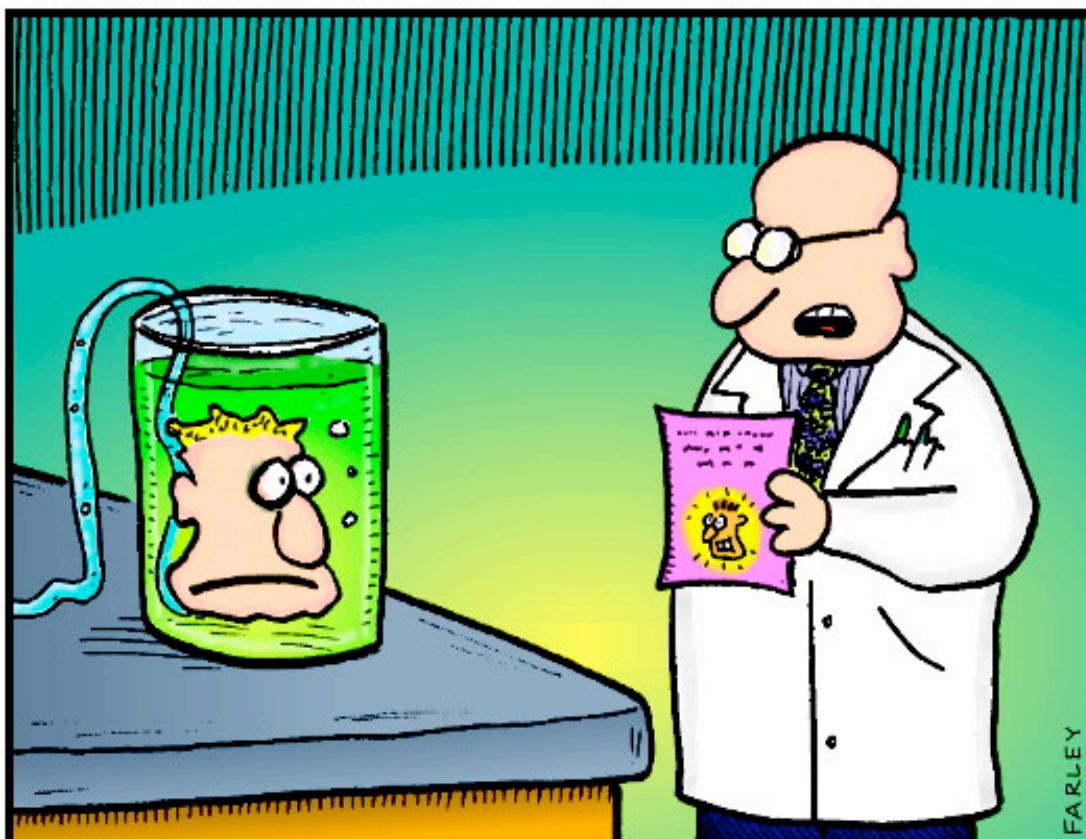
- Developed before the study opens
- Staff
  - Strategies to reach community doctors
  - Training: psychosocial aspects of diagnose on patient
- Patients
  - Education materials
- Communities
  - Community outreach
  - Strategies to reach under represented communities

A Grassroots Organization Providing Awareness & Action

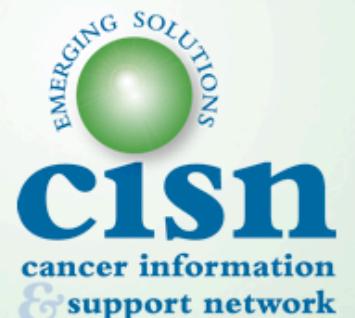


# A Bad Brochure Can Make Matters Worse

**DOCTOR FUN**



"Perhaps you'd like to read this informative booklet, So - You've Just Woke Up From Cryogenic Suspension and Now You're a Disembodied Head In a Jar."



# Old Style vs. New Style

## MRI of the Contralateral Breast

*ACRIN Research Study 6667*

An ACRIN Research Study for Women with a Recent Diagnosis of Breast Cancer

*Information for Participants*



American College of Radiology Imaging Network

Add a picture

## Breast MRI Study

*Imaging your cancer-free breast*



Are you a breast cancer patient with concerns about your healthy breast?

Don't use words people don't understand

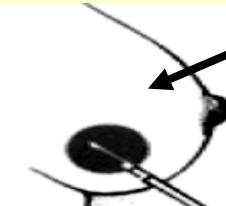
Ask a question



A Grassroots Organization Providing Awareness & Action

# New Type of Pt Focused Brochure

developed by Peggy Devine

<p><b>Understanding Your MRI and Biomarker Study</b></p>  <p>For more Information Call: <b>Advocate:</b> <b>MRI CRA:</b> <b>Trial CRA:</b></p>	<p><b>Your MRI</b></p> <p>MRI is similar to a CT scan but uses magnetism instead of X-rays to build up cross-sectional pictures of your body. Since there is no radiation, you do not need to be concerned about having several MRI scans.</p> <p>You will be given an injection of dye into a vein in the arm to improve the image. During the test you will be asked to lie very still on a bed inside a long chamber for up to an hour.</p>  <p>This can be a little frightening if you don't like enclosed spaces; if so, it may help to mention this to the radiographer.</p> <p>The MRI scanning process is also noisy, but you will be given earplugs.</p> <p>Try to relax!</p>	<p><b>Your Core Biopsy</b></p> <p>In a core needle biopsy, the physician makes a small skin incision through which a needle is inserted into the lesion to obtain sample tissue. This procedure is done under local anesthesia in a doctor's office or outpatient facility.</p> <p>A small amount of tissue is collected with a special spring-loaded device placed over the site of the tumor.</p> <p>A small bandage covers the biopsy site for several days.</p> <p>You may experience some bruising and discomfort for a short period of time.</p> 
---	--	--

**Explanation  
of  
Procedures**

**Pictures**



*A Grassroots Organization Providing Awareness & Action*

*Are you an ovarian, primary peritoneal or fallopian tube cancer patient whose tumor has become resistant to platinum chemotherapy?*

*You may be eligible to participate in a new study.*



Clinical Trial Education Series (CTES)

# Patient Focused Brochure Developed for Genentech

Ask a question

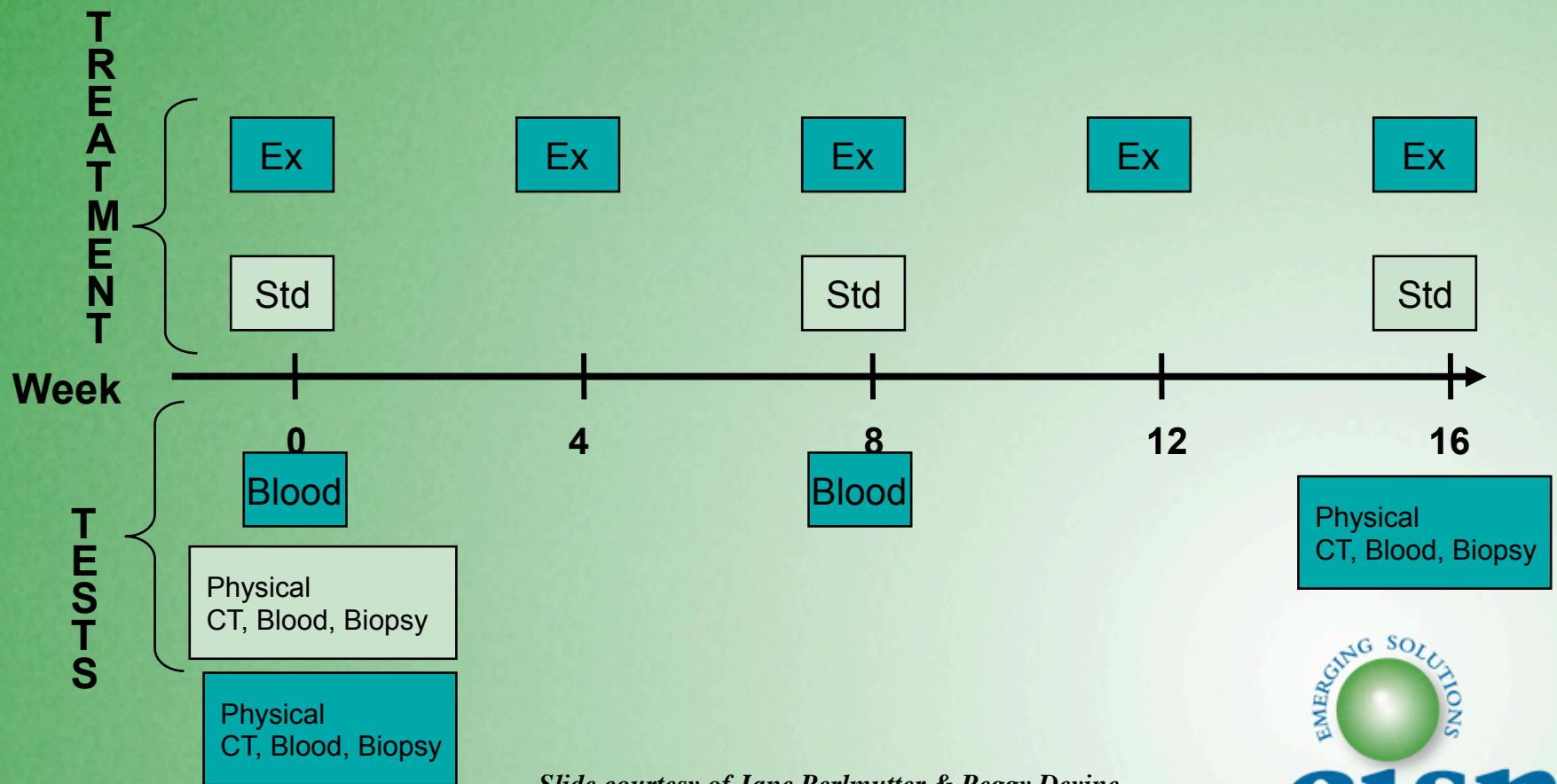
Add A Picture

*developed by Peggy Devine*

A Grassroots Organization Providing Awareness & Action



# Example: Phase 3 Patient Schedule



Slide courtesy of Jane Perlmutter & Peggy Devine

A Grassroots Organization Providing Awareness & Action



# An Effective Accrual Plan

- Developed before the study opens
- Staff
  - Strategies to reach community doctors
  - Training: psychosocial aspects of diagnose on patient
- Patients
  - Education materials
- Communities
  - Community outreach
  - Strategies to reach under represented communities

A Grassroots Organization Providing Awareness & Action



# **How to Reach Out to Under Represented Communities**

- Use the leaders already established in the community
- Develop new leaders from within the community
- Partner with: academic / cancer or community centers / non profits
- Go into:
  - Schools
  - Churches
  - Beauty parlors / barbershops

## **Recommendations?**

---

*A Grassroots Organization Providing Awareness & Action*



# A Good Communication Plan

- Developed before the study is activated
- Pre study
  - Work with advocates
  - Work with non profits representing that organ site
  - Work with community leaders and other established groups
- During Study
  - Continue above
  - Send yearly thank you's to patients
  - Create a website for PI's, staff and pt's to access
- Post Study
  - Send final pt thank you
  - Report of findings
  - Reminder to check website

---

A Grassroots Organization Providing Awareness & Action



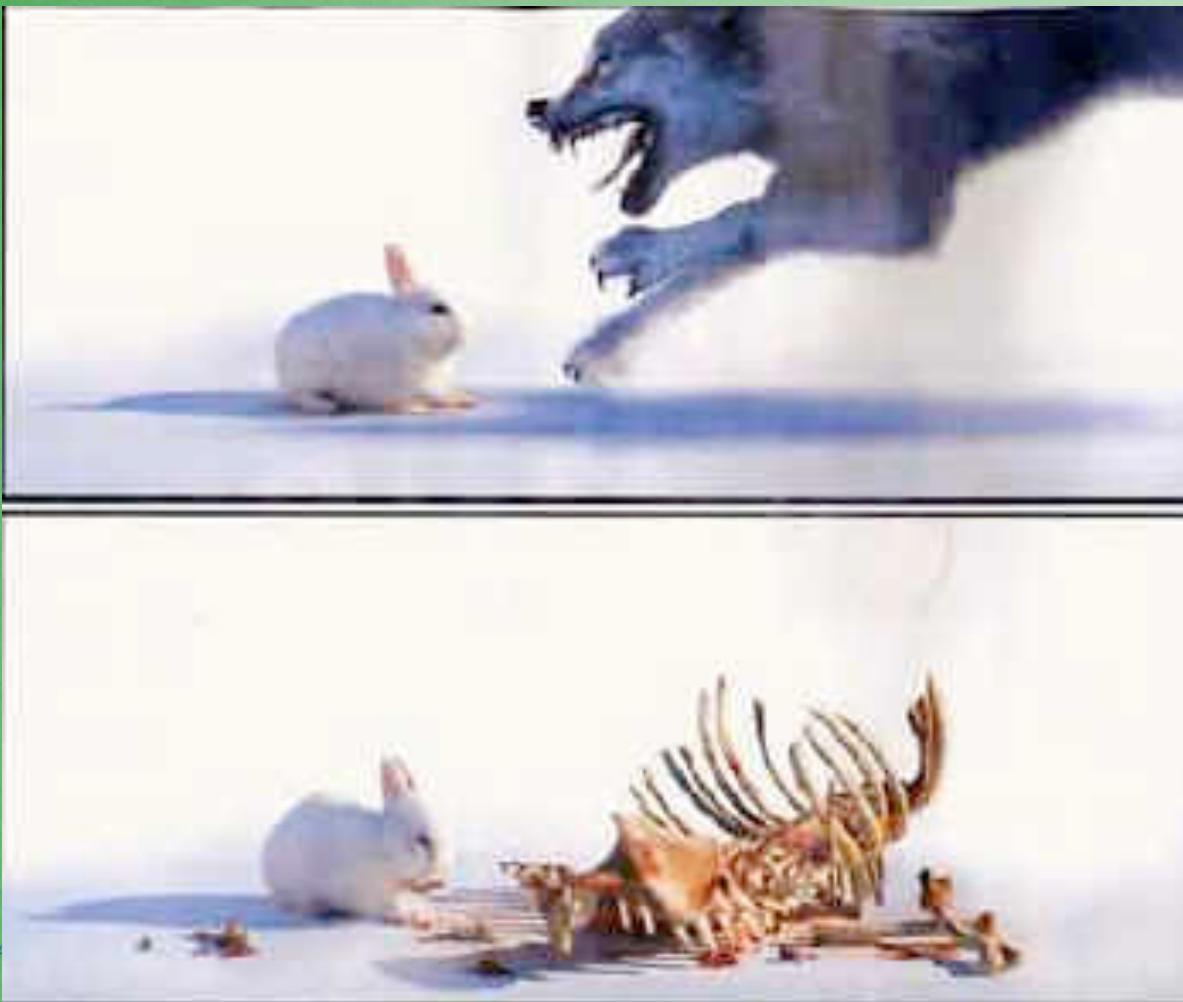
# I Know That This Feels Like A Stretch



# No Patient Should Feel Stuck Like This



## **There are Times When advocates Feel Under Appreciated**



**BUT  
don't take it  
seriously**





**Together we can make  
a difference, Thank You**



*A Grassroots Organization Providing Awareness & Action*

**c1sn**  
cancer information  
& support network