

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

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C3 ASCO advocate training

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FOCUSING on the PATIENT

Science Focus

- Introduction
- Study Objectives

Design Focus

- Randomization
- Measurement of Effect
- Study Parameters
- Statistical Considerations

Clinical Focus

- Treatment Plan
- Drugs
- Pathology Review
- Molecular Assessment

Patient Focus

- Schema
- Selection of Patients
- Informed Consent
- Recruitment Plan
- Communication Plan

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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**

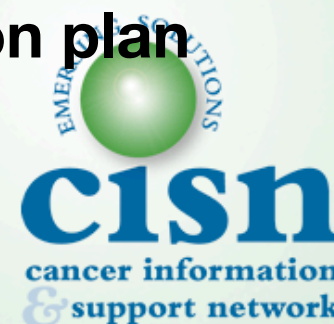
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APPROACH

- **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

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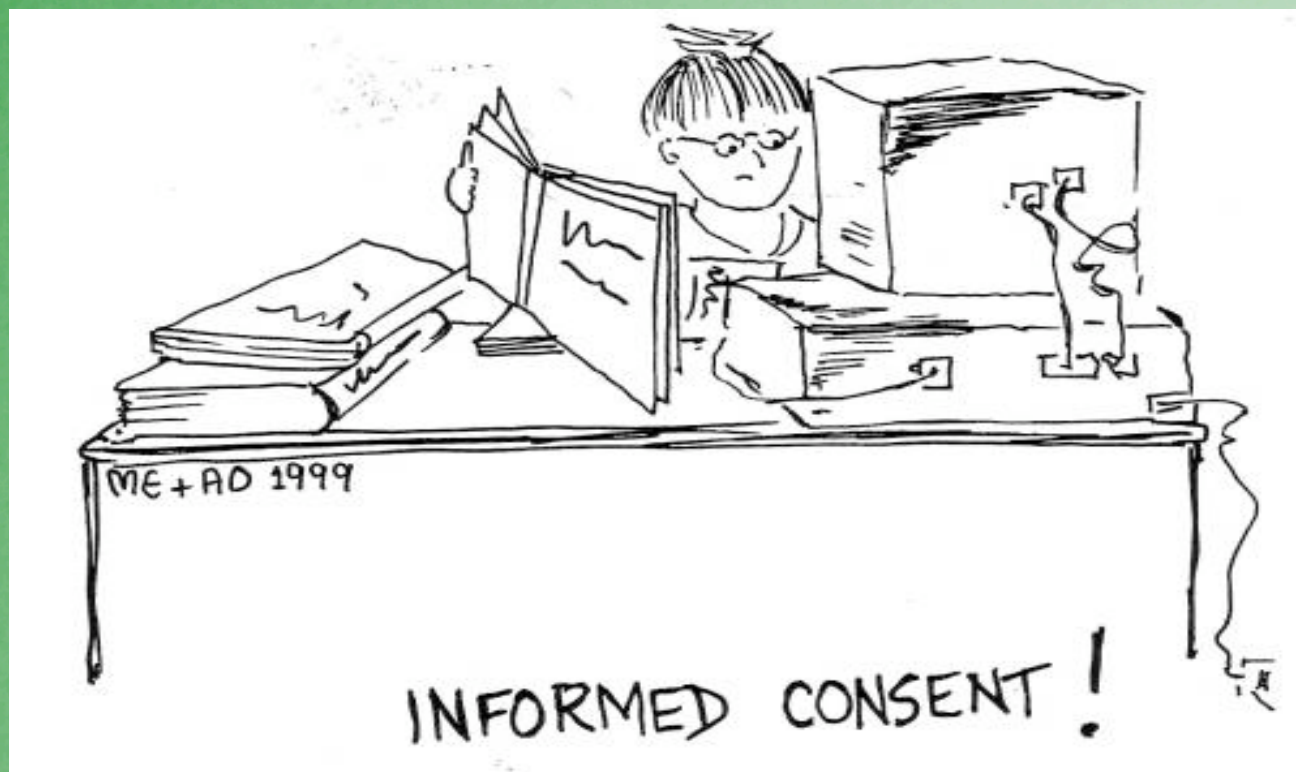
What 5 Things Would Patients Need to Know About Study Before Enrolling

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

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This Is Not What You Want



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ALL PATIENTS ARE THE SAME



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

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EACH PATIENT IS UNIQUE



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

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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

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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

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**An INTERACTIVE
INFORMED CHOICE PROCESS**

Where Do Advocates Come In?



Researchers (bench)



Advocates can be the bridge

For all translational research



Patients (bedside)

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Collaboration is Always Better



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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

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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**

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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

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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

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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)
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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

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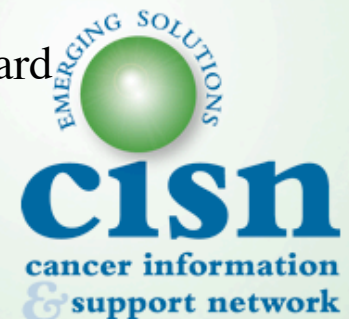


Does this Study Tell the Patient What Standard of Care Is?

- **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

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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?

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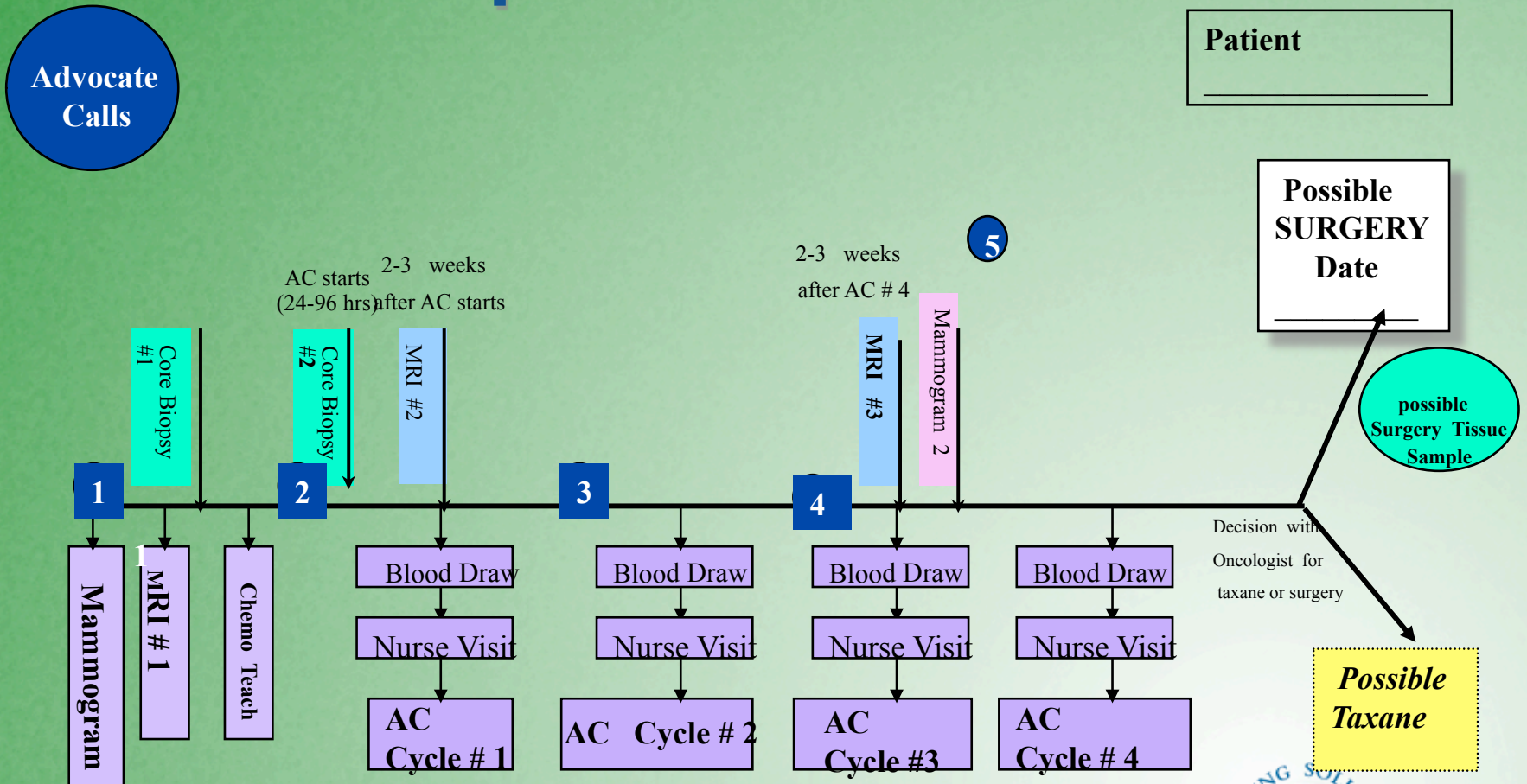


Patient



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Example # 2 of schema

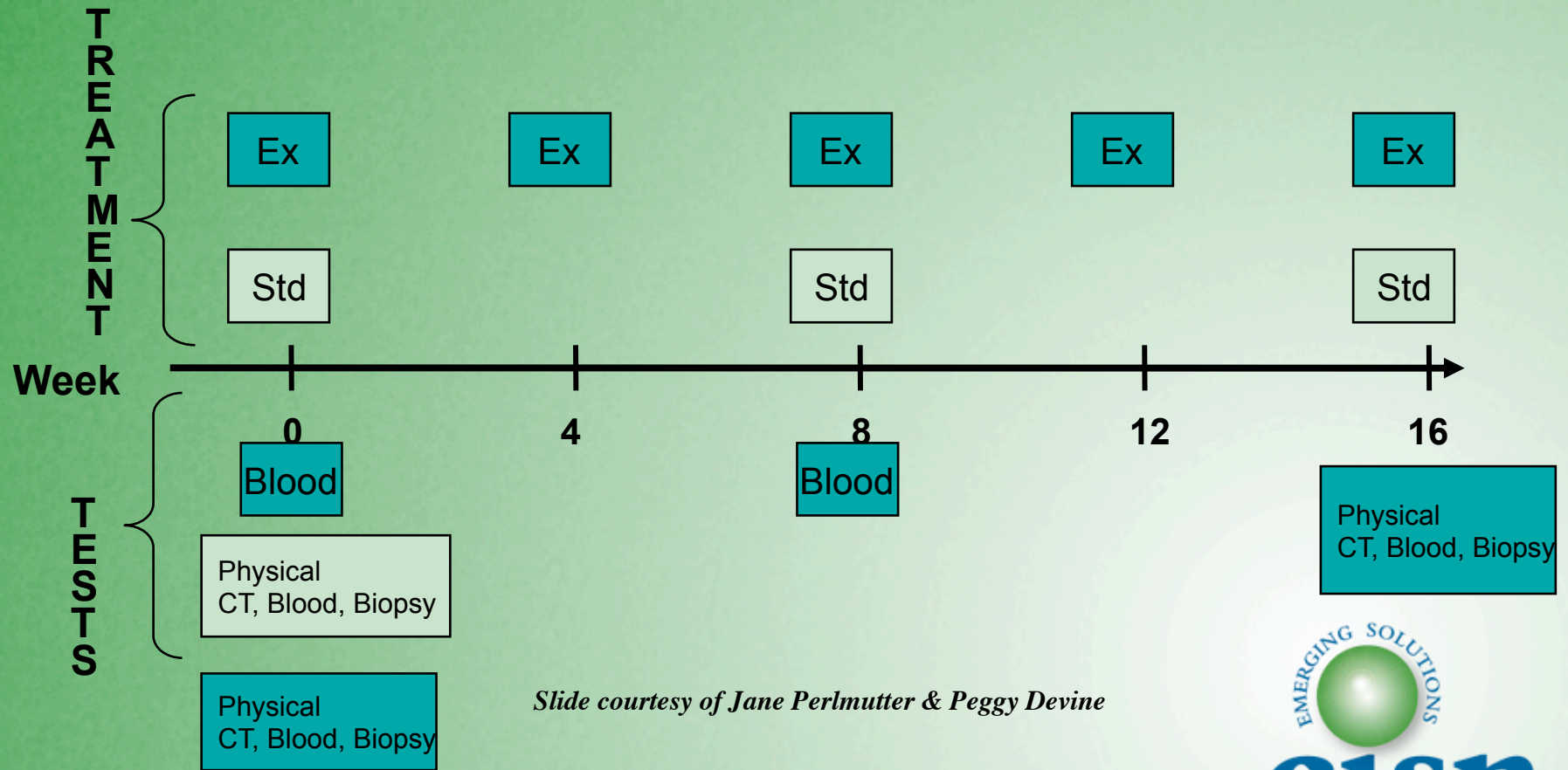


STANDARD TREATMENT : you are responsible for making all appointments

Study timeline developed by Peggy Devine

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Example: Phase 3 Patient Schedule



Slide courtesy of Jane Perlmutter & Peggy Devine

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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

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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"> • rash • fatigue 	<ul style="list-style-type: none"> • <i>anemia</i> • <i>nausea</i> 	<ul style="list-style-type: none"> • infection
Drug y	Standard	<ul style="list-style-type: none"> • hair loss 	<ul style="list-style-type: none"> • <i>low white cell count</i> • <i>vomiting</i> 	<ul style="list-style-type: none"> • heart damage • blood clot
Blood Draw	Standard	<ul style="list-style-type: none"> • mild pain 	<ul style="list-style-type: none"> • bruising 	
Bone Marrow	Experimental	<ul style="list-style-type: none"> • pain 	<ul style="list-style-type: none"> • infection • bruising 	<ul style="list-style-type: none"> • <i>allergic reaction</i> • hitting a nerve

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

Green Italics: indicates side effects are generally resolved with additional drugs

Plain: indicates other known side effects

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Informed Consent Literacy

Generally:

- Most consent forms are written at 10-16th grade reading level.
 - **Use plain English at the 6th - 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 – 6th grade reading level ~
- Use word substitution list

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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



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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**

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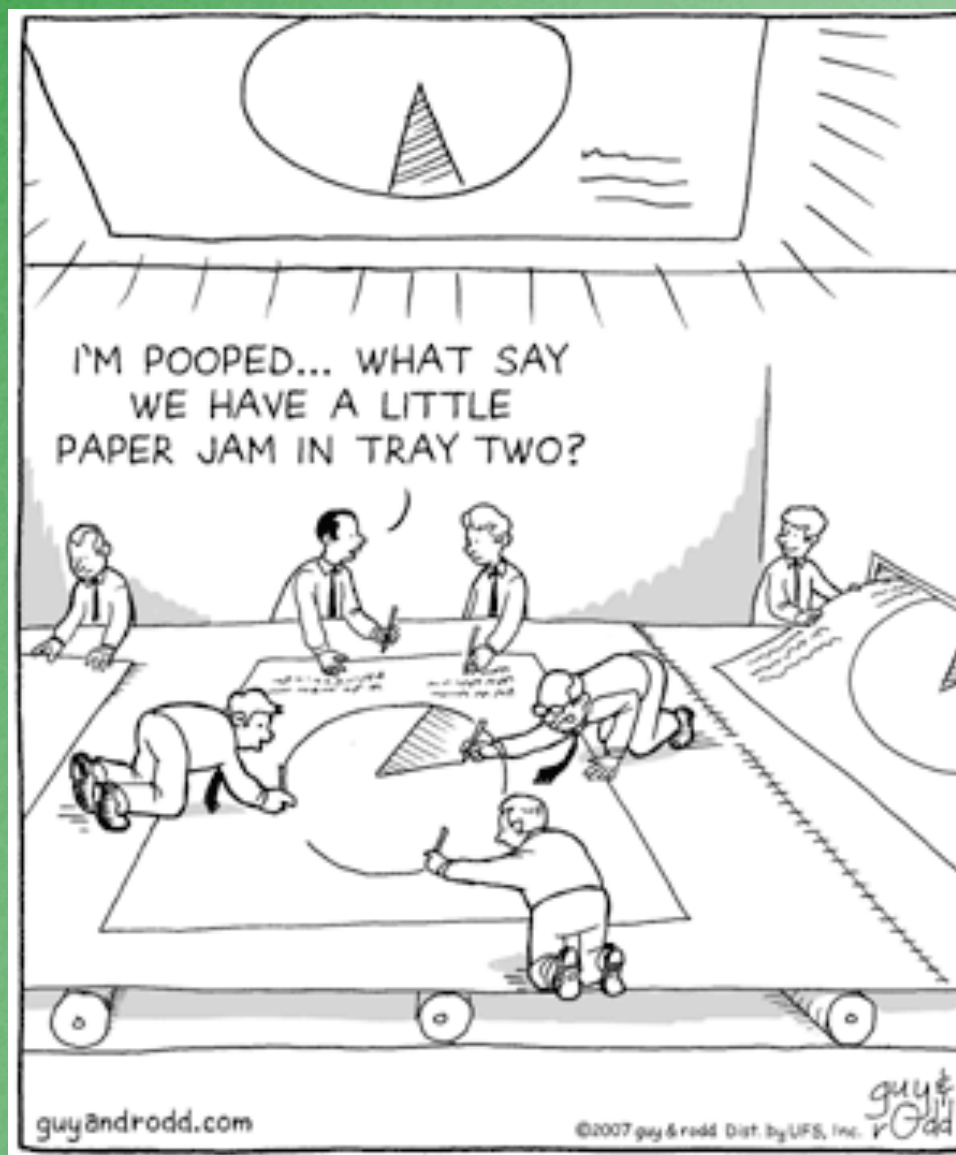


What 5 Things would Patients need to know about this Study before Enrolling

- **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**

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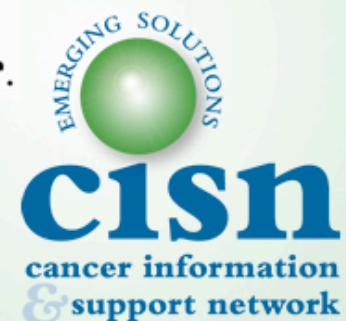




Stuff to do when you have cancer...

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

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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

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Developed before the study opens

- NO indication of this

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An Effective Accrual Plan

- Developed before the study opens

- **Staff**

- Strategies to reach community doctors
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An Effective Accrual Plan

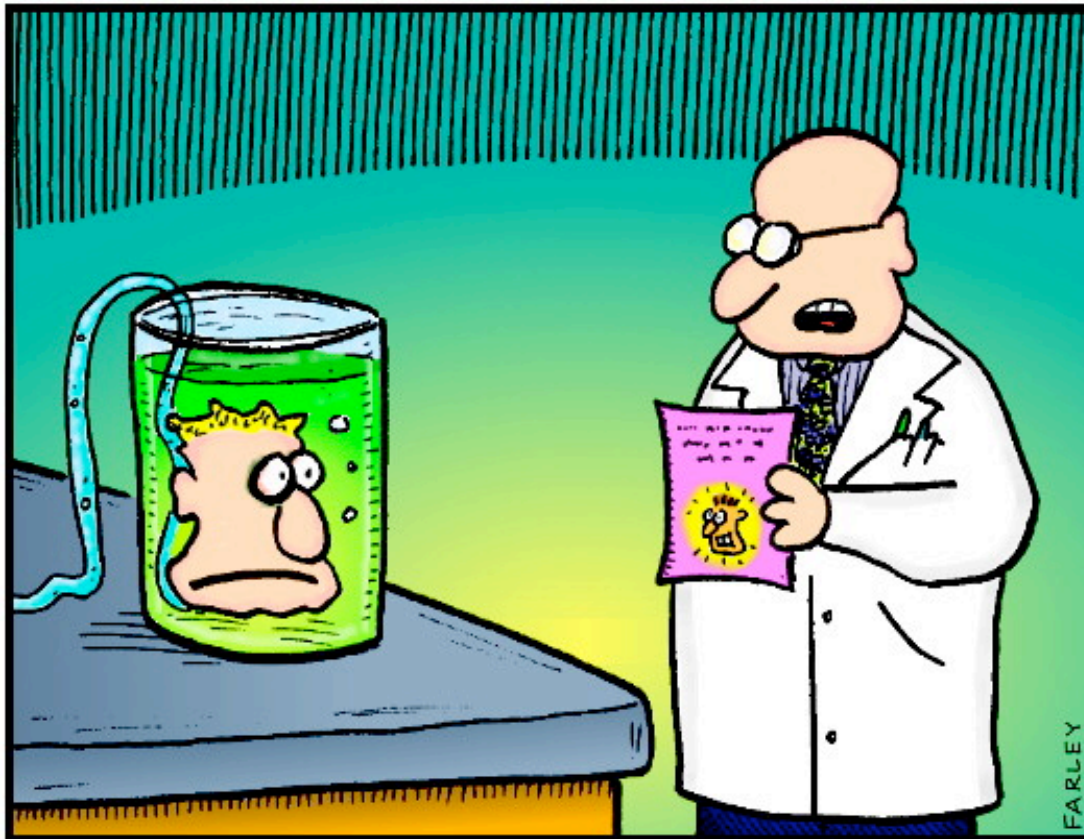
- **Developed before the study opens**
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A Bad Brochure Can Make Matters Worse

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*

acrin American College of Radiology
Imaging Network

Breast MRI Study
Imaging your cancer-free breast



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

acrin American College of Radiology
Imaging Network

**Don't use
words people
don't
understand**

**Add a
picture**



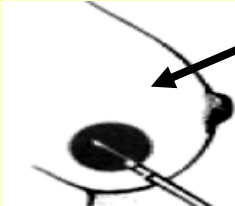

**Ask a
question**

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New Type of Pt Focused Brochure

developed by Peggy Devine

<p>Understanding Your MRI and Biomarker Study</p>  <p>For more Information Call: Advocate: MRI CRA: Trial CRA:</p>	<p>Your MRI</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>Your Core Biopsy</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> 
	<p>Explanation of Procedures</p> <p>Pictures</p> 	

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Patient Focused Brochure Developed for Genentech

*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)

Ask a question

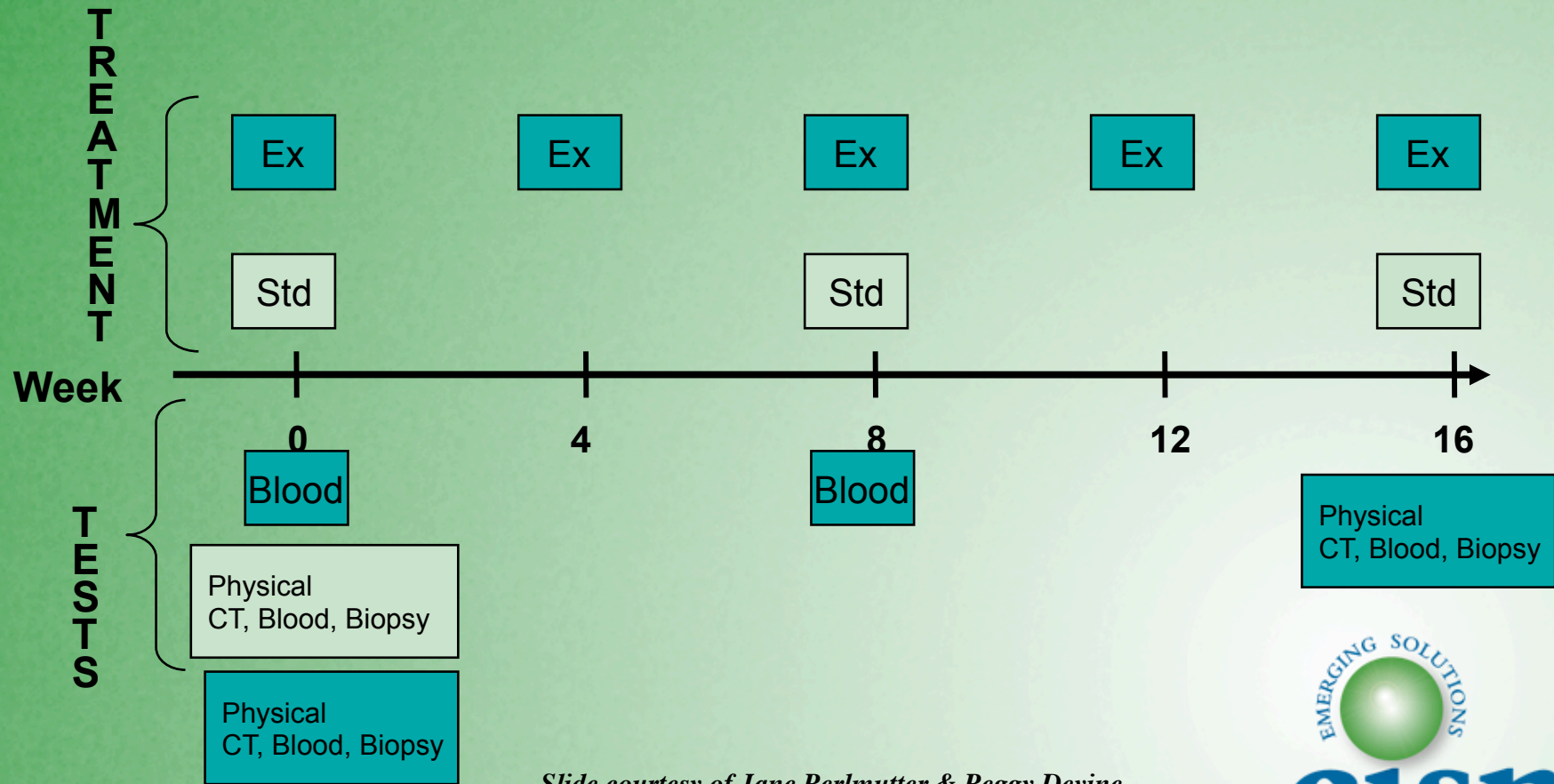
Add A Picture

developed by Peggy Devine

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Example: Phase 3 Patient Schedule



Slide courtesy of Jane Perlmutter & Peggy Devine

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An Effective Accrual Plan

- Developed before the study opens
- Staff
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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?

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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

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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**



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c1sn
cancer information
& support network