

Informed Choice

It's hard (1 in 5 clinical studies are published – most from failure to accrue.) You have what the **sponsor** of the drug wants and other **team** members, **budget** restrictions, the design challenges – it has to answer the question (good science), it has to be a **reasonable therapeutic decision** for the patient, you may have a limited study population with increasing # of competing protocols, and then you have also the consent process:

At the end of the day it's patient acceptance that will determine if the study gets completed - buy-in from the treating physicians.

What might be a good outcome for the patient? –and how does that fit with patient expectations? Manage the disease – delay relapse? Cure? Provide relief from symptoms?

The goal of the informed consent document is that it's read and understood - that it helps the patient to make an informed choice.

Discussion points:

The IC document is part of a larger process that should also involve significant other

If you are the PI, put on your physician hat ...

The process is not rushed; should be interactive

How to judge comprehension?

Ask patient to restate in own words? Ask for main questions?

What does this patient understand about her condition and options?

What are the patient's expectations?

Helping each patient having unique preferences to make an informed choice

Based on sufficient information or reasonable expectations

Put study in context of all reasonable choices

* Focus on difference between the study and regular care

Treatment risks, tests, biopsies, time, supporting evidence, limits and risks of regular treatment

* Known risks compared to standard – uncommon, less likely, unlikely

What will you do to monitor for and minimize?

IC Document should be **readable** and not too long – if needed, provide supplemental information to help keep the consent document short.

Expected outcomes of usual approach

Uncertainties with study protocol – may be no better, equal or worse.

Schema of treatment and tests

Calendar is good: Day | What you do

Put complex information in tables. Use bulleted lists.

Procedures – biopsies, labs, exams

Risk? Pain? How many? Burdensome? Cause apprehension?

• **NCI:** Include procedures? Risks of procedures?

– *Only if part of research question, not if part of "usual approach"*

• **NCI:** Text provided for mandatory specimen collection, within primary consent, and optional specimen collection, located before signature line

Closing: Next step – take time to review and discuss. Welcome questions at any time. The CI should provide **Contact information for study doctor**

– **Contact information for study doctor**

"Who can answer my questions about this research study?" section ask questions, discuss concerns, report side effects or injuries

Laboratory Correlates

You're going to do what – how many times?

At the end of the day it's patient acceptance that will determine if the study gets completed - or buy-in from treating physicians.

So for the study team it's important to anticipate issues and appreciate the practical impacts of the laboratory procedures: the **burden to the patient**. The apprehension associated with biopsies and other procedures, and **how that can affect accrual**.

Does regular care or other studies look equally promising and ask less of me?

Increasingly the **analysis of tissue or blood** can be integral or integrative to the study design– such as to determine eligibility, or the potential for benefit or harm from a targeted drug, to know if drug is getting to target, or to identify new targets for a condition that has no effective care. On the importance of predictive markers to pts, is there anything worse than have the disease it is also getting toxicity and no benefit (unproductive toxicity)

Integral: essential for study define eligibility, stratification, disease monitoring or study endpoints (CLIA)

Each study is unique ... so I encourage you to seek input from advocates when you have questions and concerns.

I can't cite a study but I feel that concern about the disease trumps privacy concerns. Patients will want to contribute tissue if the case is made.

That said, we research advocates have concerns about future use

With molecular and DNA analysis the implications of donating tissue has changed dramatically. In the wrong hands the findings can be stigmatizing to the family, not just the patient. So ownership, protection of privacy and consenting are very important issues.

I think **NCI Best Practice** is good; however it may not be **implemented widely across different centers**. Look up: OBBR: NCI Best Practices for Biospecimen resources

We advocates (probably not the overwhelmed newly diagnosed patient) want to see **more collaborative tissue-based research** with standardized capture, analysis, and sharing of data – informatics systems that advance knowledge while protecting privacy.

Exploratory studies should be done in cooperative group?

This use of tissue could improve the consent rate as it will make it much more likely that the donated tissue will help to make progress against the disease –

but also, possibly for the patient a collaborative biospecimen system will **open additional opportunities to participate in clinical research**.

Collaborative research seems key to successfully correlative study – as does advocacy to increase incentives to do biomarker assays ... **financial reward**.

NCI informed Consent template At-a-Glance

NCI_IC_Template Revised 5-12-13 Clean Final.doc

NCI strongly recommends that consent forms not exceed **six to nine** pages.

Focus on what makes the study different from the care a patient would typically receive.

Use of active voice, short sentences, personal pronouns, clear page layout with "white space" borders, and large fonts make documents easier to read. The use of simple outlines, flow charts, diagrams, study schemas, calendars, and other graphics are encouraged.

OVERVIEW - Checklist

<p>Study Title for Study Participants: (Lay Title)</p> <p>Official Study Title for Internet Search on www.ClinicalTrials.gov</p> <p>What is the usual approach to my condition</p> <p>What are my other choices if I do not take part in this study?</p> <p>Why is this study being done?</p> <p>What are the study groups?</p> <p><i>If randomized:</i> "A computer will by chance assign you to treatment groups in the study. This is called randomization. This is done by chance because no one knows if one study group is better or worse than the others." (add simplified scheme)</p> <p>How long will I be in this study?</p> <p>What extra tests and procedures will I have if I take part in this study?</p> <p>What possible risks can I expect from taking part in this study?</p> <p>COMMON, SOME MAY BE SERIOUS In 100 people receiving FOLFOX, more than 20 and up to 100 may have (bullet list here)</p> <p>What possible benefits can I expect from taking part in this study?</p> <p>Can I stop taking part in this study?</p> <p>What are my rights in this study?</p> <p>What are the costs of taking part in this study?</p> <p>What happens if I am injured or hurt because I took part in this study?</p> <p>Who will see my medical information?</p> <p>Where can I get more information?</p>	<p>ADDITIONAL STUDIES SECTION: (Indicate clearly to participants that this is a separate section)</p> <ol style="list-style-type: none"> 1. Optional imaging study – extra scan This example pertains to an extra scan for research purposes) 2. Optional imaging study – research scan or This example pertains to an investigational scan or procedure. 3. Optional Quality of Life Study 4. Optional Sample Collections for Laboratory Studies and/or Biobanking for Possible Future Studies <p>WHAT IS INVOLVED? If you agree to take part, here is what will happen next: 1) Choose applicable sentence for the trial: About (insert number) tablespoons of blood will be ...</p> <p>WHAT ARE THE POSSIBLE RISKS? 1) The most common risks related to drawing blood ...</p> <p>HOW WILL INFORMATION ABOUT ME BE KEPT PRIVATE?</p> <p>ARE THERE ANY COSTS OR PAYMENTS?</p> <p>WHAT IF I CHANGE MY MIND?</p> <p>SAMPLES FOR THE LABORATORY STUDIES:</p> <p>SAMPLES FOR FUTURE RESEARCH STUDIES: My samples and related information may be kept in a Biobank for use in future health research.</p> <p>YES NO</p> <p>I agree that my study doctor, or their representative, may contact me or my physician to see if I wish to participate in other research in the future.</p>
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Discussion

What I have planned for our program development session is to ask each of you to provide replies to one or more of the following questions - as you would say it to an elderly patient or child - as you would also write it in your informed consent document:

1) **What is the name of the trial in lay language (Testing ...)**

NCI: To make title concise, list the usual approach generically; e.g., chemotherapy, radiation therapy, surgery; rather than providing specific names, e.g., docetaxel, IMRT, laparoscopy.

NCI example: "Testing the addition of the antibody, cetuximab, to usual chemotherapy in advanced lung cancer"

2) **What is the usual approach to my condition?**

NCI guidelines say that you can be fairly broad and generic; where appropriate, include expected outcome if usual approach is utilized.

NCI: ... clinical trials generally assume a usual approach that the research hopes to improve upon. Providing a brief description of a usual approach, which should not be overly specific or detailed, allows the research to be placed into an appropriate context. Whenever appropriate, include an estimate of the expected outcome for usual approach.

3) **What extra tests and procedures will I have if I take part?**

NCI: Most of the exams, tests, and procedures **YOU** will have are part of the usual approach for **YOUR** cancer. However, there are some extra ... (examples in bulleted list)

4) **Why are you doing this research (scientific rationale)?**

NCI guidelines: limit to 5 or 7 sentences (You have... The purpose of this study is to test ... There will be about N people taking part in this study.

Clinical trials generally assume an approach that the research is aimed at improving ... *"This will allow the researchers to know whether the new treatment is better or worse than the usual treatment."*

5) **How long will I be in this research study?**

While this may seem a relatively minor question, it could be decisive information when participation is a close call - and it may influence how likely it is that the patient would stay on study if consent is given.

Will I still be able to work or go to school?

6) **What risks can I expect from taking part?**

Group by:

Common, occasional, rare and serious, serious, possible, some may be serious

NCI example:

Occasional, Some May Be Serious

In 100 people receiving XYZ, from 4 to 20 may have