INFORMED CONSENT

CAN’T WE DO BETTER?

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INFORMED CONSENT
WHAT DOES THAT MEAN?

• Document?
• Process?
• Signature?
REGULATORY REQUIREMENTS FOR OBTAINING **EFFECTIVE** CONSENT

- 8 must haves (12, depending upon how you count)
- 6 maybes
- In a language that is understandable
CONSENT DOCUMENT
MUST HAVES

1)  
a)  A statement that the study involves research  
b)  Explanation of the purpose(s)  
c)  Expected duration of participation  
d)  Description of procedures  
e)  Identification of procedures which are experimental

2)  Description of reasonably foreseeable risks or discomforts

3)  Description of reasonably expected benefits

4)  Alternative procedures or treatments

5)  Confidentiality of records

6)  For greater than minimal risk research – availability of compensation and/or medical treatment if injury occurs

7)  Whom to contact with questions or to report injury

8)  Participation is voluntary
CONSENT DOCUMENT
MAYBES

1. Unforeseeable risks
2. Circumstances that might cause the investigator to stop a participant’s participation
3. Additional costs to the participant
4. Consequences of withdrawal
5. Significant new findings
6. Approximate number of participants involved

But who decides “when appropriate”? 
CONSENT DOCUMENT

• Provides a baseline of information
• A reference source during the study
• Documents agreement to participate

“Think of the document primarily as a teaching tool not as a legal instrument.”

OHRP: Tips on Informed Consent
http://www.hhs.gov/ohrp/policy/ictips.html
WHAT’S THE PROBLEM?

• Reading level too high
• Filled with technical, legal and medical information
• Short and understandable is hard to do
• Focus on being inclusive instead of informative
• Emphasis placed on the document instead of the process
IRB’s request:

Please define “placebo” so that a lay person can easily understand it.

Investigator’s response:

A placebo is a blank pill of innocuous substance used to test the efficacy of the active capsule.
The study doctors cannot promise that your participation in this study will result in any direct or immediate benefit to you.

You may or may not receive a benefit from being in this study.

You will receive $50 each time you see the study doctor.

While you are in this study child care will be provided.

Because you are in this study you will get better medical care.
Description of reasonably foreseeable risks or discomforts?

- Previous studies with *** have included healthy volunteers, and subjects with diseases of the liver (including Hepatitis C). Healthy subjects have received oral doses of *** ranging from 1 mg to 500 mg per day. People with liver disease have received multiple oral doses up to 200 mg twice a day for 14 days and 50 mg twice a day for 12 weeks. Most of the side effects were mild to moderate but a limited number were described severe.

- There is clinical safety experience with a different preparation which also contains *** as well as another compound that is given with *** intravenously (by vein) which is approved only for patients with *** disorders. *** disorders are inherited errors in metabolism that result in very dangerous increases in ammonia in the blood due to partial or complete lack of enzymes needed to remove ammonia from the circulation resulting in coma and mental damage and disability in some cases. *****, which is the preparation specifically for *** disorders (which is a very different condition than yours), contains sodium and cannot be given through an arm vein because of the risk of tissue damage (it requires that a line be placed centrally). ***** is not approved for your condition and is given for emergency treatment of *** disorders at a **** dosage 1 to 4 times higher than the content of *** provided in *** at the dosages planned in the current *** study. However, since ***** contains *** (although given to a different type of patient in a different manner and in another chemical form), it is important to make you or your relative (or individual for whom you are the legally authorized representative) aware of the adverse events that have been reported with ***** in patients with *** disorders which most frequently include vomiting (throwing up) (9% of patients), high blood sugar (7%), low blood potassium (7%), seizure (6%), mental impairment (6%), and brain swelling (5%). All additional adverse events occurring in ≥ 3% of 316 patients with *** disorders in the FDA label were the following: anemia (4%), problems clotting (3%), diarrhea (3%), nausea (3%), fever (5%), reaction (problem) at infusion site (3%), high ammonia (5%), urinary tract infection (3%), acidosis (low blood pH) (3-4%), low blood calcium (3%), coma (3%), agitation (restlessness) (3%), trouble breathing (3%), and low blood pressure (4%).
Appropriate alternatives that might be advantageous?

• There are alternatives to this study. One alternative is to not participate in this study. Another alternative is to have other treatments.
• Your alternative is not to participate in this study.
CONSENT PROCESS
CONSENT PROCESS

• Who
  Who will conduct the consent discussion?

• What
  What will they be told?

• When
  When is the consent discussion taking place?

• Where
  Where will the consent discussion take place?

• How
  How will it be done?
WHAT’S THE PROBLEM?

• No regulatory framework
• No “best practices”
• Every study is different
• Every investigator is different
“I go up to a patient and say. “Hi, we’re doing a study, would you like to hear about it?” If they say yes, I give them the consent document, tell them to read it and let me know if they have any questions. I know it’s important to give them time to think, so I leave and come back in 10 or 15 minutes. When I come back I ask them if they signed it.”
SURELY WE CAN HELP
CONSENT DOCUMENT

What can we do?

• Take advantage of regulatory flexibility
• Put information in order
• Use headers/sub-headers
• Bullet/chart
• Say it once
• Present information consistently
• Insert diagrams/pictures
• Phased consent documents
• KISS
• Know when to let it go
  ❖ Pay attention to formatting and grammar when it matters, but it doesn’t always matter
Adolescent Assent To Participate In Research
University of Mississippi Medical Center

[Title]

1. Why am I here?
   You are being invited to be in an experimental research study, because
   ×

2. Why are they doing this study?
   × To gain more information about how well the

3. What will I have to do?
   [Describe]
   □ You will come back to see the study doctor [visit schedule].
   □ At these visits, the study doctor will listen to your heart and lungs, look at
     your eyes, ears, nose, mouth and legs, and feel your belly.
## Schedule:

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<tr>
<td>Visit 4</td>
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## Important Things to Remember:

1. 
2. 
3.
Chapter Five: Bad Things

Sometimes kids don’t feel well after they take the medicine.

They might feel these things:

Headache

Coughing
Pregnancy You may not participate in this program if you are pregnant or breast-feeding. Pregnancy tests will be done on all women able to become pregnant before beginning the study. The cost of this test will be paid for by the study sponsor. If you are able to become pregnant, you must use an acceptable method of birth control such as birth control pills, condoms, or a diaphragm together with spermicidal foam or gel throughout the study and 30 days after the last dose of study medication has been given.

If you become pregnant during this study, please notify the study doctor immediately. You will be withdrawn from the study and we will discuss additional treatment for your disease with you.

Benefits You may or may not receive direct benefit from this research study. It is possible that your infected wound will heal. Through your participation, we hope to learn information that will help others in the future.

Alternatives If you choose not to participate in this study, your disease will be treated with our usual treatment which includes surgery followed by treatment with other drugs similar to the study drug. There will be no additional costs to you for participating in the study. The study sponsor will cover the costs for any study medication, tests, examination, or other procedures that are solely done for research purposes. The rest of the medical care that you receive in this study is considered standard care for your situation and would be recommended whether or not you participate in this study. These costs will be billed to you or your insurance carrier.

COMPENSATION

Coming in for a final study visit means that you will have to make an extra trip to the hospital. You will receive $5000 to compensate you for your time and any out of pocket expenses.

VOLUNTARY PARTICIPATION Your participation in this study is voluntary. If you decide not to participate in this study, you will not suffer a penalty or loss of benefits to which you are otherwise entitled. If you decide to participate in this study, you may withdraw from the study program at any time without penalties or loss of benefits. This will not affect the quality of medical care you will receive.

WITHDRAWAL You may choose to withdraw from this study program. Please discuss this with your study doctor to help ensure your safe withdrawal from the study. Your participation in this study may be discontinued by your study doctor without your consent for the following reasons:

If you do not follow the study doctors plan of care.
**PREGNANCY**
You may not participate in this program if you are pregnant or breast-feeding. Pregnancy tests will be done on all women able to become pregnant before beginning the study. The cost of this test will be paid for by the study sponsor. If you are able to become pregnant you must use an acceptable method of birth control, such as birth control pills, condoms or a diaphragm together with spermicidal foam or gel through out the study and 30 days after the last dose of study medication has been given.

If you become pregnant during this study, please notify the study doctor immediately. You will be withdrawn from the study and we will discuss additional treatment for your disease with you.

**BENEFITS**
You may or may not receive direct benefit from this research study. It is possible that your infected wound will heal. Through your participation, we hope to learn information that will help others in the future.

**COST**
There will be no additional costs to you for participating in the study. The study sponsor will cover the costs for any study medication, tests, examination, or other procedures that are solely done for research purposes.
CONSENT PROCESS

What can we do?

- Have participants take a short quiz about the study
- Ask open-ended questions during the consent discussion (Teach Back)
  - Do you have any questions?
  - Do you understand?

- Tell me about some of the things you are going to have to do during this study.
- What are some of the possible risks of being in this study?
- Don’t wait until the end to ask all the questions

- Encourage potential participants to talk to friends, relatives, other disinterested 3rd party

- Informational video
TEACH BACK

• Enhances communication and helps confirm understanding
• Asks individual to recall or explain in his/her own words what has been discussed
• Enhances short-term and long-term recall of study-related information
• If incorrect answer given, information explained again and participant given another opportunity to demonstrate understanding
Appropriate consent process
+
Appropriate consent document
=
Effective informed consent
Hush-a-bye baby
In the tree top
When the wind blows
The cradle will rock
When the bough breaks, the cradle will fall,
and down will come baby, cradle and all.
It shall be deemed mandatory for the infant in question to cease, desist, and refrain from any and all vocal demonstrations while reposing in the uppermost regions of said tree.

The climatic conditions are such as to effect winds of such nature and to such extent that they will create an oscillating movement in the sleeping accommodation of said infant.

Such meteorological conditions shall induce the fracturing of the branch supporting said facility thereby ultimately causing the rapid descent of same.

There shall be a downward plunge of the sleeping apparatus, bringing with it the reposed infant perilously contained within, along with all objects, paraphernalia, and debris directly related to the above-mentioned baby and cradle.

*Adapted from The Legal Guide to Mother Goose, Translated by Don Sandburg*
The party of the first part, hereinafter known as “****”; and the party of the second part, hereinafter known as “***”, ascended or caused to be ascended an elevation of undetermined height and degree of slope, hereinafter referred to as the “hill”. Their purpose was to obtain, procure, secure, or otherwise gain or acquire by any and/or all means available to them a receptacle or container, hereinafter known as “a pail”, suitable for the transport of a liquid whose chemical properties shall be limited to two parts hydrogen and one part oxygen, the proportions of which shall neither be less than nor exceed the amount specified for each element. Such combination shall hereinafter be called “water”.

On the occasion stated above, it has been established beyond a reasonable doubt that *** did plunge, tumble, topple, stumble, drop, plummet, fall down, dive, pitch, collapse, fall over, or otherwise lose his footing in a manner that caused his body to be thrust into a downward direction. As a direct result of these combined circumstances, **** suffered fractures and contusions to his cranial regions. ***, whether due to ****’s misfortune or not, was known to also tumble plunge, topple, stumble, drop, plummet, fall down, dive, pitch, collapse, or fall over in similar fashion after ****. (Whether the term “after” shall be interpreted in a spatial or time passage sense has not yet been determined.)

*Adapted from The Legal Guide to Mother Goose, Translated by Don Sandburg
Jack and Jill
Went up the hill
To fetch a pail of water
Jack fell down
And broke his crown
And Jill came tumbling after.
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