

Medical Research Summit

Welcome and Introduction

Medical Research Summit

- Michele Russell-Einhorn
- Robert “Skip” Nelson
- Tom Puglisi

- The job of the IRB is to be ever vigilant.
- That's not always easy.

Investigators will obtain the fully
informed consent of the subject



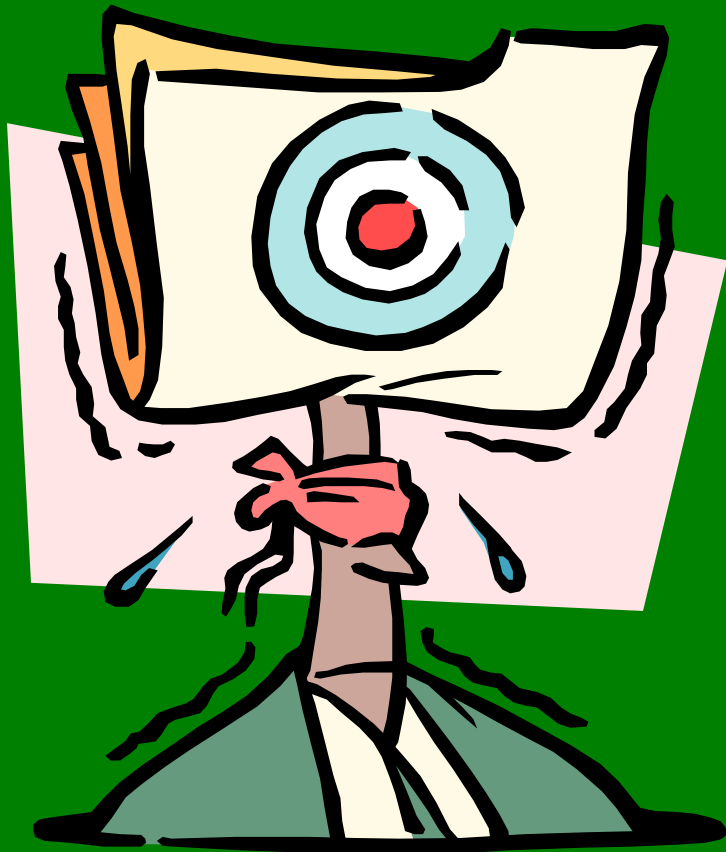
Investigators will obtain the fully informed consent of the subject



- Informed consent will be obtained shortly after the anesthetic has been administered.

Subject May Withdraw Freely at
Any Time

Subjects May withdraw Freely at Any Time



- The device that has been implanted in you is set to explode if you decide to withdraw from this research.

There are alternatives to
participating in this research

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- The alternative is not to participate in this research and get the standard of care treatment which is 10% effective with an 8% remission rate for successful responders after three months.

Do not make any subject waive or appear to waive any of their rights

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- You do not give up any legal rights by participating in this research except that you give up ownership of every blood, tissue or other sample now or forever after linked to this research and any commercialization thereof...

The Benefits of the Research Should not be Overstated

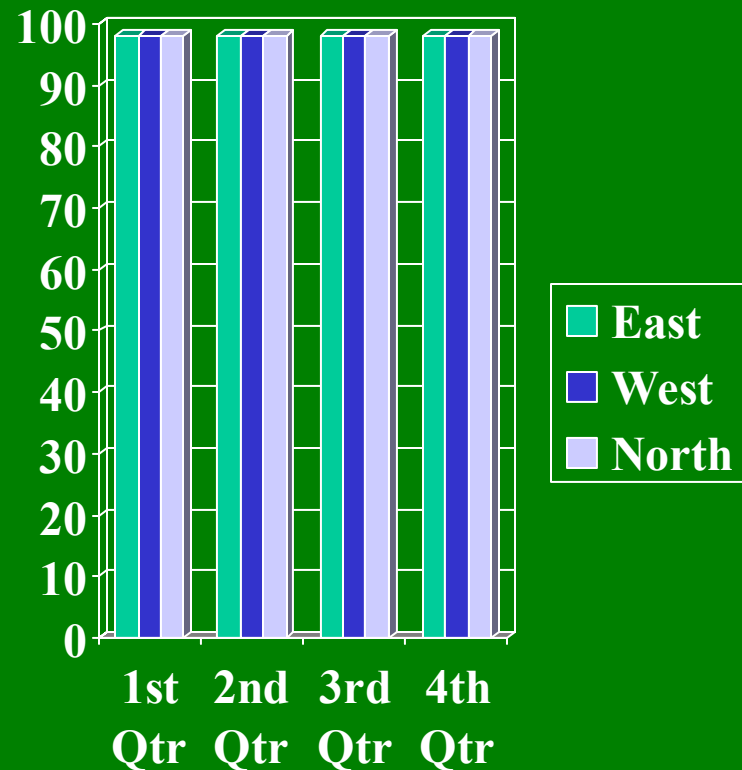
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- The benefit of participating in this research is that you will be cured.

Subjects Should not be Coerced
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- It is anticipated that 98% of the population recruited will agree to participate in the research.



Anonymous means that there are
no identifiers maintained

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- This research is anonymous because only my research team will know the names of the subjects.

Compensation to Subjects should
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- You will receive \$5 for each of the four visits and \$1000 if you complete the entire research protocol.



Unanticipated Problems Involving Risks to Subjects and Others

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- The dog ate my data and is suffering toxic shock from chemicals on the paper.
- The lab technician drank the experimental alcohol compound instead of the orange juice on the counter.
- The subject revealed that his father is in the federal government's witness protection program.

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