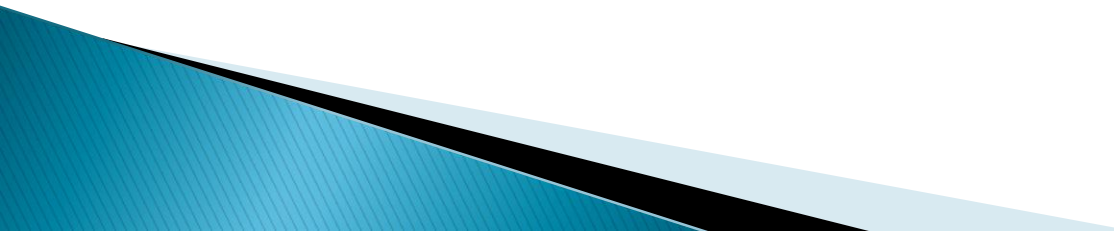


Informed Consent: Principles and Problems

Charles W. Lidz Ph.D.



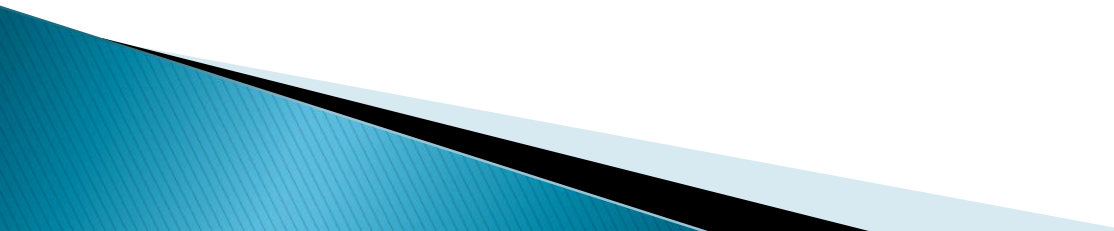
Informed Consent: Law and Ethics

- ▶ Law is about duty – these are the things everyone MUST do.
 - ▶ Ethics is about aspiration – these are the things that you should do to be an outstanding person.
 - ▶ There are reasons that law should not demand too much of us – think Prohibition
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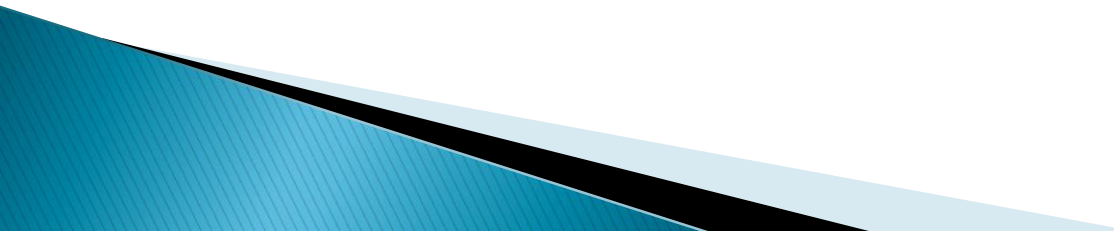
What is this Informed Consent Stuff about?

- ▶ Law
 - requires disclosure
 - does not require understanding
- ▶ Ethics
 - calls for dialogue
 - Mutual participation in decision making

What **disclosure** does informed consent require?

- the **nature** of the proposed procedure
 - the **purpose** of the procedure
 - the **risks**
 - the **benefits**
 - any **alternatives** to the proposed procedure
- 

What do we Disclose about Clinical Research?

- ▶ The primary **purpose** of research is to gather **valid data** that will provide an answer to an important research question
 - ▶ Both legally and ethically, we are required to make that clear.
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Contrasting Clinical Trials and Ordinary Treatment

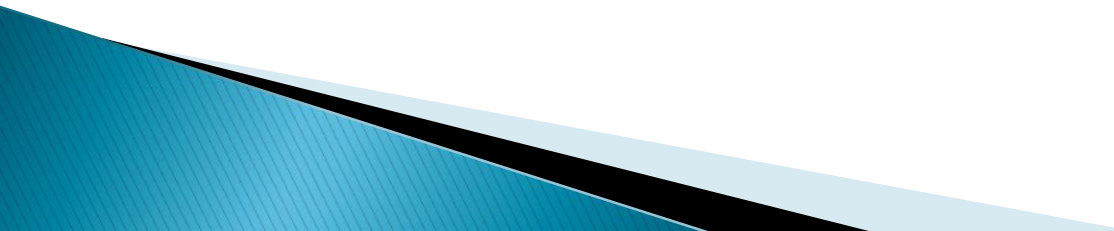
▶ Treatment

- ▶ Individualized Tx decisions
- ▶ Physician selects Tx for pt. benefit
- ▶ Other treatments used if thought helpful
- ▶ Dosage adjusted for maximum benefit
- ▶ Tx chosen to be effective

▶ Clinical Trials

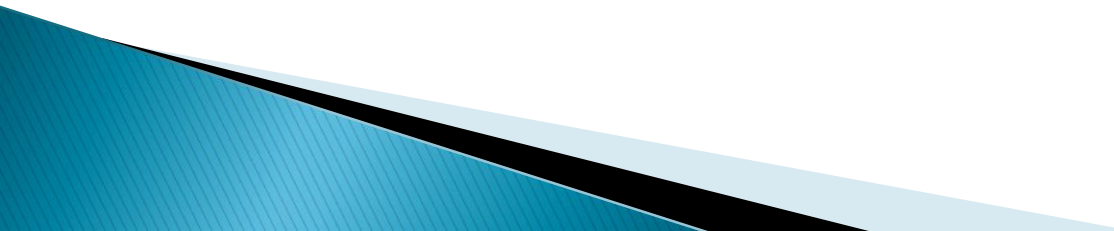
- ▶ Randomized assignment
- ▶ Physician blinded
- ▶ Restrictions on other treatments
- ▶ Limited adjustment of dosage
- ▶ Use of placebos

These are Important Limits

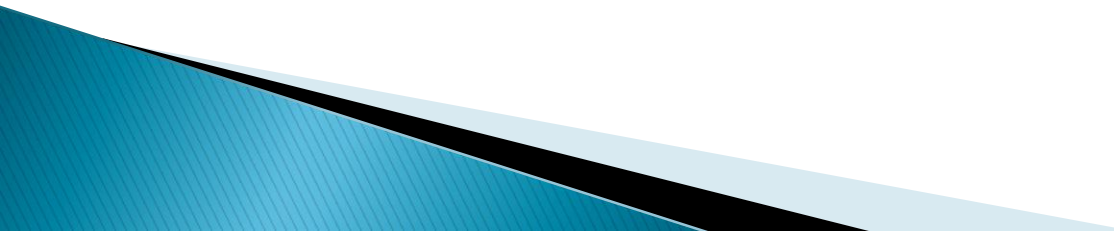
- ▶ Researchers do not impose these limitations lightly
 - ▶ They are essential for gathering generalizable data
 - ▶ Research staff often monitor care better
 - ▶ Nonetheless, these are important risks that subjects should consider when enrolling
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The Therapeutic Misconception (TM): A Definition

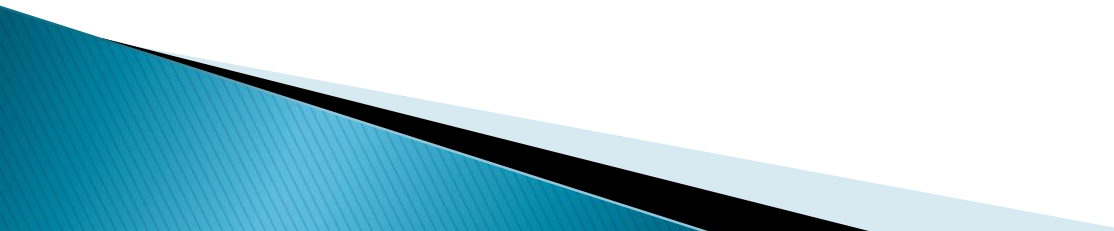
The ***therapeutic misconception*** occurs when a research subject fails to grasp the **distinction between clinical research and ordinary treatment** and attributes therapeutic **intent** to research procedures



The Discovery of TM

- ▶ Paul Appelbaum and I were interviewing and taping subjects who were in clinical trials
 - ▶ Woman was getting all the details right
 - ▶ Could not believe that her doctor would randomize treatment
- 

An Empirical Study of TM

- ▶ Paul Appelbaum, Tom Grisso and I set out to describe the frequency and the correlates of TM
 - ▶ 243 subjects, 44 different studies, 2 sites
 - ▶ Semi-structured interviews
 - ▶ Education averaged 14.2 years
 - ▶ Most in phase III clinical trials
- 

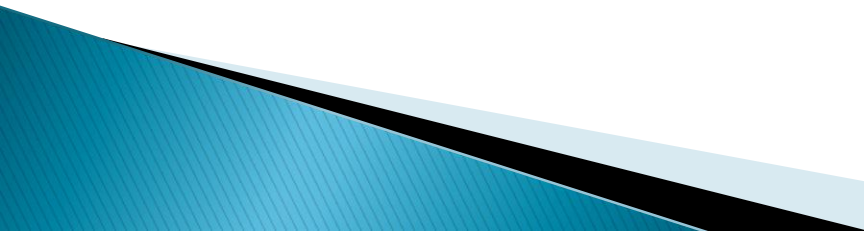
Measuring the Therapeutic Misconception

- ▶ Text of interviews is coded for two features:
 - the belief that the treatment would be individualized to the subject
 - an unreasonable assessment of benefit (i.e. one precluded by the design of the study)
- ▶ Found **62% of a sample of research subjects met one criterion or both**

Understanding of Risks

- ▶ Critical Interview Question:
“What, if any, are the risks or disadvantages of being in this study”
- ▶ Coded entire text for statements about risks and disadvantages
- ▶ Looked only at clinical trials
N=149

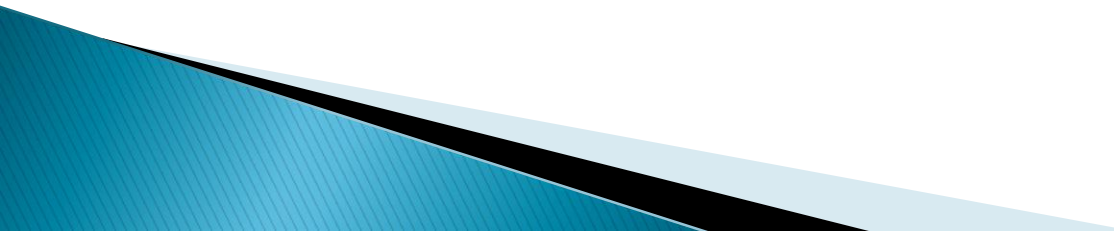
Risk Codes

- ▶ Risk inherent in **Research Design**
 - ▶ Risk inherent in **Experimental Treatment (i.e. side effects)**
 - ▶ Risk of **Routine Treatment**
 - ▶ **Incidental Disadvantages**
 - ▶ Risks **Minimized or Partially Denied**
 - ▶ **Complete Denial of Risk**
- 

Results: Denial

- ▶ 18.8% denied any risks or disadvantages
- ▶ 14.7% were in partial denial or minimized risks; e.g., I hope there aren't.... They could make mistakes... the treatment could be wrong but I assume they[will] correct [it]"

Risks of Treatment

- ▶ 8.7% of sample reported only risks associated with standard care
 - ▶ Largest group (36.2%) reported side effects of the experimental intervention
 - ▶ These subjects had no apparent awareness of risks associated with the **design** of clinical trials
- 

Risks of the Research Design

- ▶ 18.1% of subjects reported some awareness of the risks involved with the research design
- ▶ Examples:
 - 11 subjects expressed some concern about possibly getting a placebo (including 4 who reported other concerns about clinical trials)
 - 4 subjects expressed concerns about the double blind design.

Three Possible Interpretations

- ▶ Subjects are incompetent – Not all subjects
 - ▶ Poor or deceptive disclosures
 - ▶ Subjects are confused by their expectations that they will be treated as patients
 - ▶ **Needed: New techniques of disclosure focusing on the implications of the research methods for subjects' care.**
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