Informed Consent

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What is Informed Consent?

- "when information is disclosed
- to a competent person
- [who] will understand the information and
- voluntarily
- make a decision

(Meisel, Roth, & Lidz, 134 Am. J. Psychiatry 1977; 134:285-9.)

"In your case, Dave, there's a choice – elective surgery, outpatient medicinal therapy, or whatever's in the box that our lovely Carol is holding."

What are the Purposes of I/C?

- Solemnity
- Conveys *respect* for individual
- Enables S to exercise *self-determination*
- Promotes subject *safety*
- Limits investigator authority/power
- Protects the institution

IF done right, it allows those who do not want to participate *to refuse*

Standards of Disclosure

- Historically, I/C for research developed independently of I/C for clinical care
- Various ethical standards for I/C "disclosures" have been proposed:
  - "Full" disclosure
  - Subjective person
  - Reasonable person + (subjective) negotiation (Levine)
  - Reasonable Volunteer (Belmont Report)
- But what we have is a Regulatory Standard

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Regulatory Standard

- FDA (20 CFR 50) and Common Rule specify:
  - Setting must allow potential Ss sufficient opportunity to consider participating
  - Free of *coercion* or *undue influence*
- Specified elements:
  - Procedures/duration
  - Risks
  - Potential benefits
  - Voluntary, right to withdraw
  - Alternatives to participation
  - Other details…

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Doesn't say who does it, how its done, or how much detail needs to be provided

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"This is going to be a little invasive."

“This is gonna hurt like hell.”

How is I/C secured?

- Truism: “Informed consent is more than a form; it is a process.”

- Processes vary:
  - Who carries out the process;
  - When is it done;
  - Where is it performed;
  - What information is (needs to be) disclosed;
  - How is information conveyed:
    - Reliance on the Consent Form as communications;
    - Repeated educational efforts;
  - Use of recall/knowledge testing

“Discouraging data on the antidepressant.”

Concerns about I/C

- Process is (often) not conducive to reflection
  - Present forms and have conversations as early and often as feasible
- Threats to voluntariness
  - Poor understanding by some Ss
    - Diminished capacity
    - Stress
    - Literacy
    - “Coerced by circumstance”
  - Conflicted physician – researcher roles

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"Mr. Wilkins, I believe that your condition is going to get us both into the 'Journal of the American Medical Association.'"

(more) Concerns about I/C

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- Threats to voluntariness
  - Poor understanding by some Ss
    - Diminished capacity
    - Stress
    - Literacy
    - "Coerced by circumstance"
  - Conflicted physician – researcher roles
  - Therapeutic misconception
    - Unrealistic expectations of personal benefit

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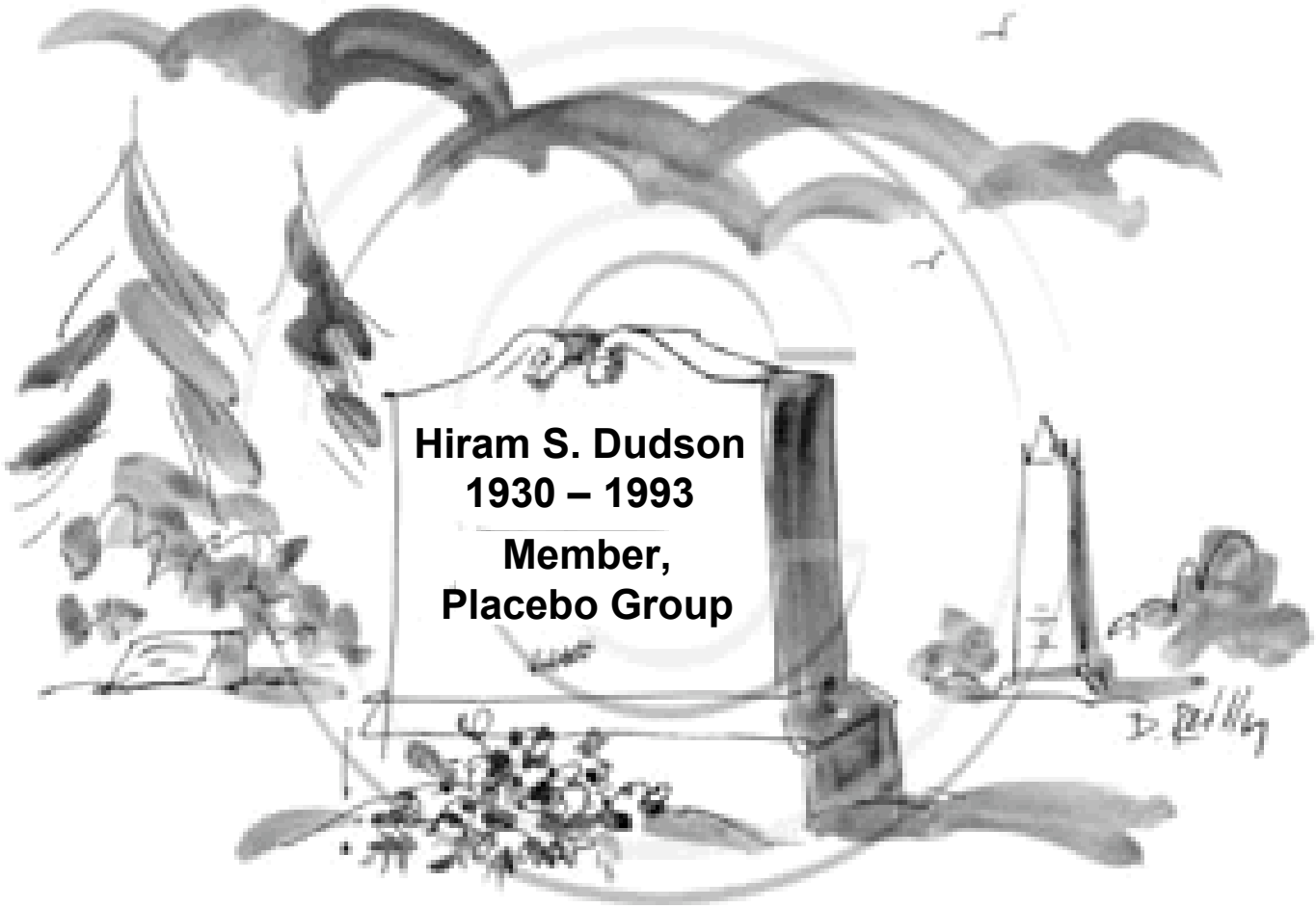
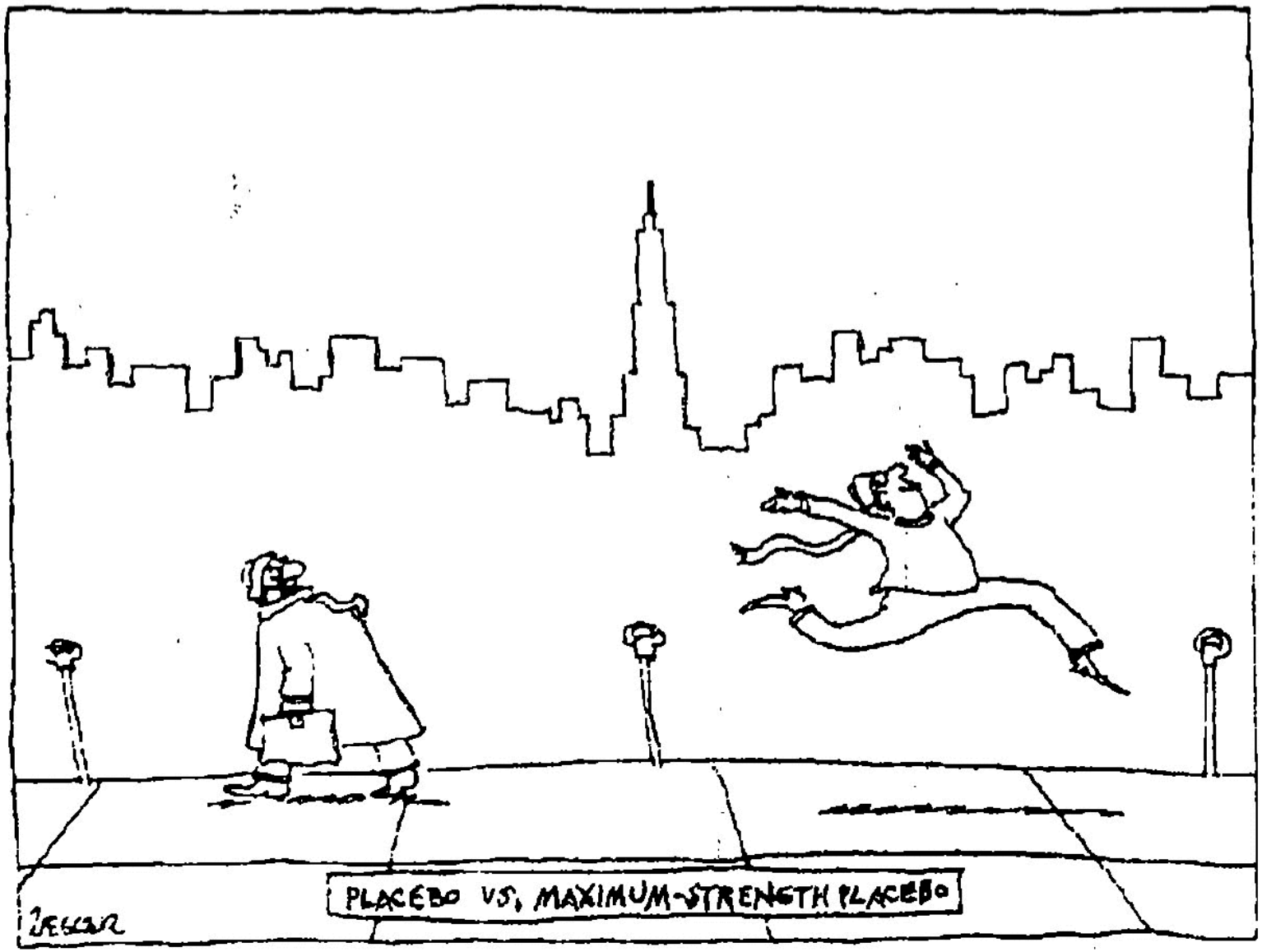
"*Scientists have extended the life of the fruit fly.*"


Hiram S. Dudson
1930 – 1993
Member,
Placebo Group



I/C Forms are Poor Communications

- Typically have *high readability* scores
- Frequent use of *technical language/jargon*
- Little use of *decision* and *risk communication aids*
- Unbalanced risk/potential benefit disclosures:
  - Risk disclosures:
    - Noncontextualized laundry list of possible (known) outcomes
  - Potential benefit disclosures:
    - Nonprobabilistic statements of hope
- Convey sense that I/C protects the institution

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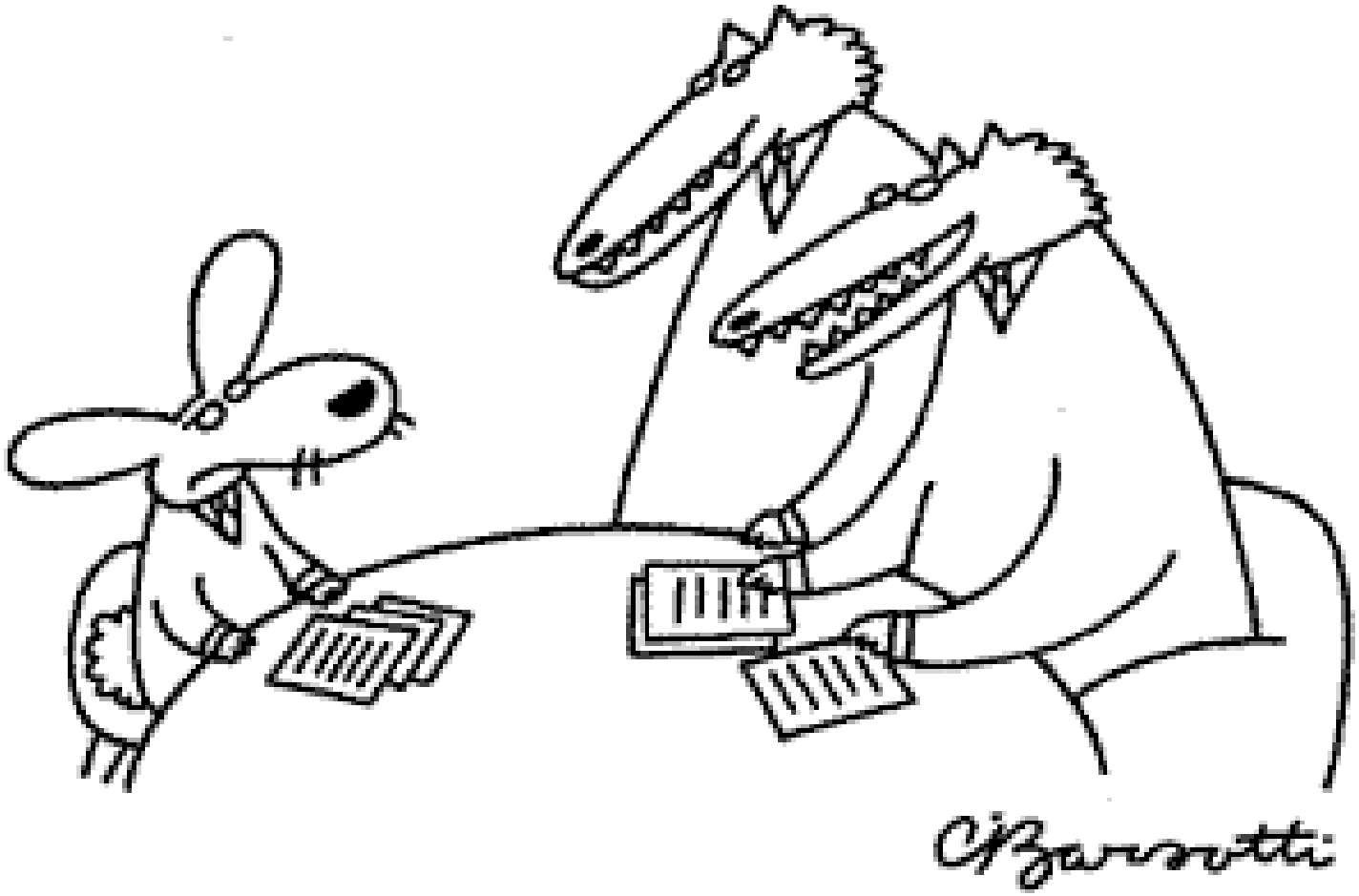
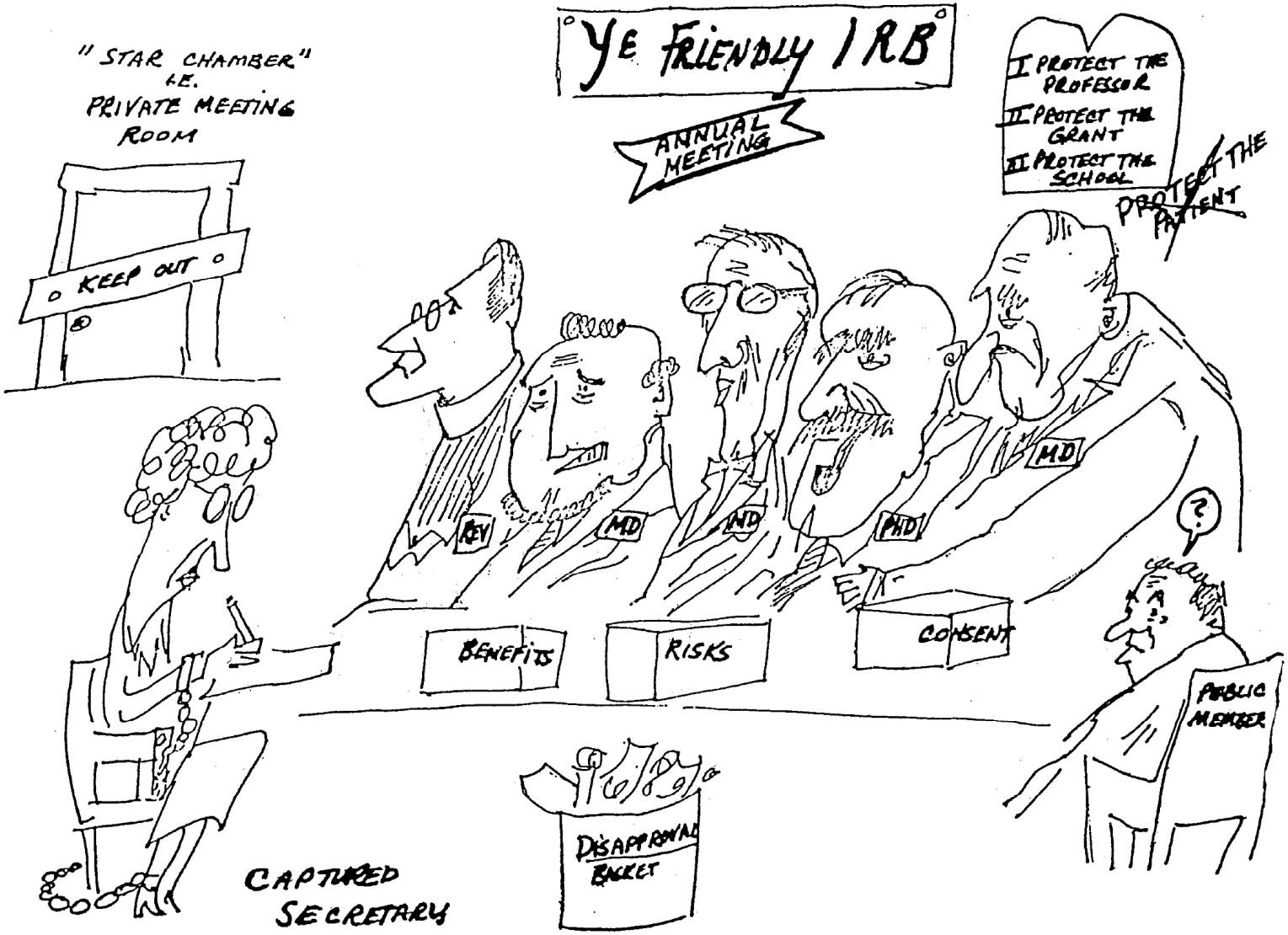


“There. Now it’s all on paper. Feel better?”

What is the IRB's Role?



By Al Jonsen

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How are IRBs doing?

- IRBs fail paternal role of protection from harm
  - poor risk/potential benefit decision-making
- IRBs focus efforts on upholding rights
  - spend most of their effort on consent forms
  - not on the *process* of consent (who, how, when)
  - several studies find IRBs make CFs more complex
    - completeness trumps clarity
- IRBs appear to protect the institution

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Can we Improve Informed Consent?

- Yes.
  - Lots of room for improvement.
  - But it's not easy.
- Various approaches are being tried:
  - Better communications/education tools
    - Interactive systems
    - Web based communications
  - Testing of knowledge
  - Using expert writers
    - Replace IRB writing-by-committee
  - Subject advocates

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