

# What Makes a Good IRB Chair?

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Medical Center



"... AND MR. FELDMORE'S MOONING OF THE OTHER COMMITTEE MEMBERS  
WAS INTERPRETED AS THE ONLY 'NAY' VOTE..."

# What do you need to be an IRB chair?

- meeting skills
- interpersonal skills
- knowledge

# Meeting skills

thanks to Fran DiMario, MD, CIP (Connecticut Children's Hospital)

- leadership and time management
  - be prepared (and anticipate issues)



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    - encourage alternative viewpoints (let people disagree)
    - encourage participation

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    - encourage participation
- stay focused
  - redirect discussion to regulatory criteria for approval and underlying ethical principles

# Criteria for IRB approval

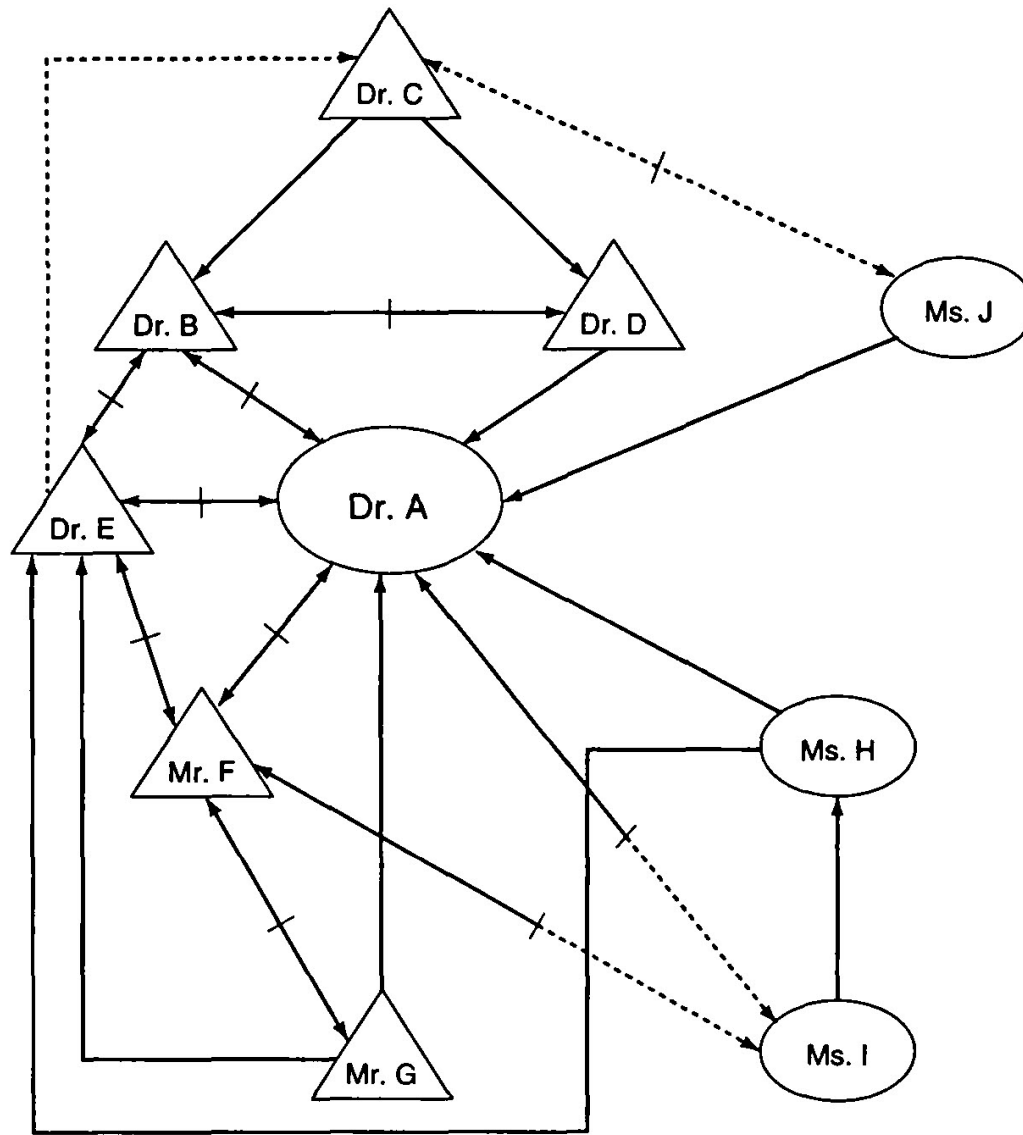


- how do members "remember" the regulatory criteria for approval?
  - checklist
  - application
  - agenda
  - PowerPoint slide
  - poster board
  - placemat

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    - encourage participation
  - stay focused
    - redirect discussion to regulatory criteria for approval and underlying ethical principles
- resolve conflict and build consensus



Key:

A: Chairperson, pediatrician, age 44

B: Psychiatrist, 61

C: Surgeon, 46

D: Radiologist, 43

E: Philosopher, 53

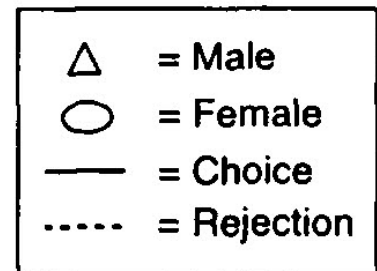
F: Lawyer, 35

G: Priest, 48

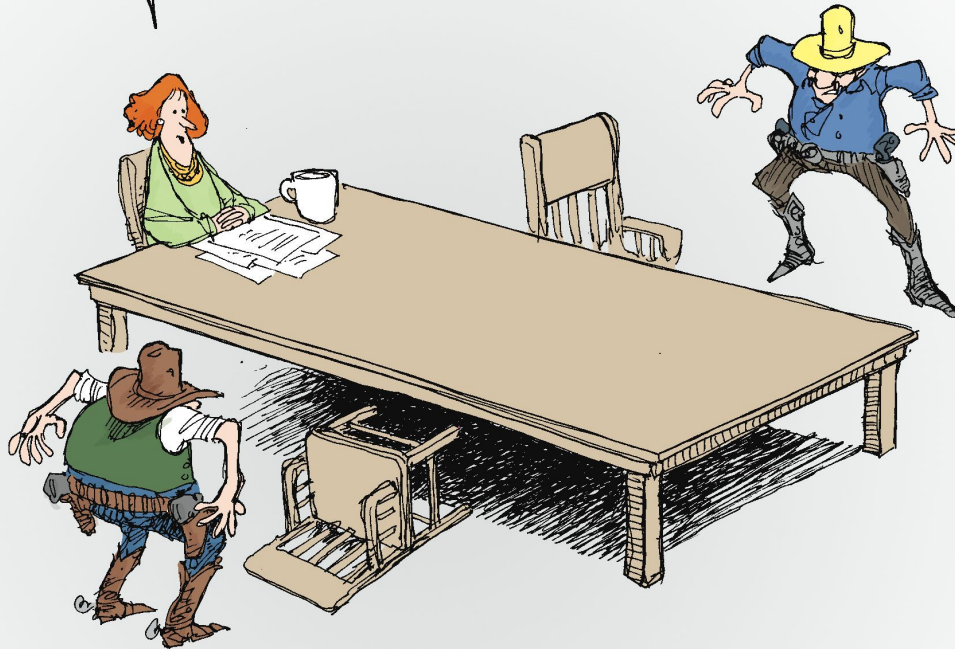
H: Chief of nursing, 56

I: Administrator, 31

J: Social worker, 48



SO YOU BOTH AGREE THAT THIS TOWN  
ISN'T BIG ENOUGH FOR THE TWO OF YOU.  
WELL, I THINK THAT SHOWS WE'RE  
MAKING PROGRESS HERE...



MEDIATION at the O.K. CORRAL

# Key elements of mediation

- Separate interests and positions:
  - **Position** is what you are asking for
  - **Interests** are the underlying needs and goals
- "this protocol needs to be tabled ..."



# Key elements of mediation

- Position ...
  - "the protocol needs to be tabled"
- Interest
  - "the consent form has many typos and grammatical errors ..."
- Possible solutions ...
  - Table the protocol
  - Approve the protocol
- Possible solutions ...
  - Table the protocol
  - Have the IRB staff revise the CF
  - Have the PI revise the CF
  - Approve the protocol

# Key elements of mediation

- Keep conflict cognitive rather than affective
  - Focus on the problem (disagreement) rather than on the person
  - Use neutral language
  - Avoid "you"



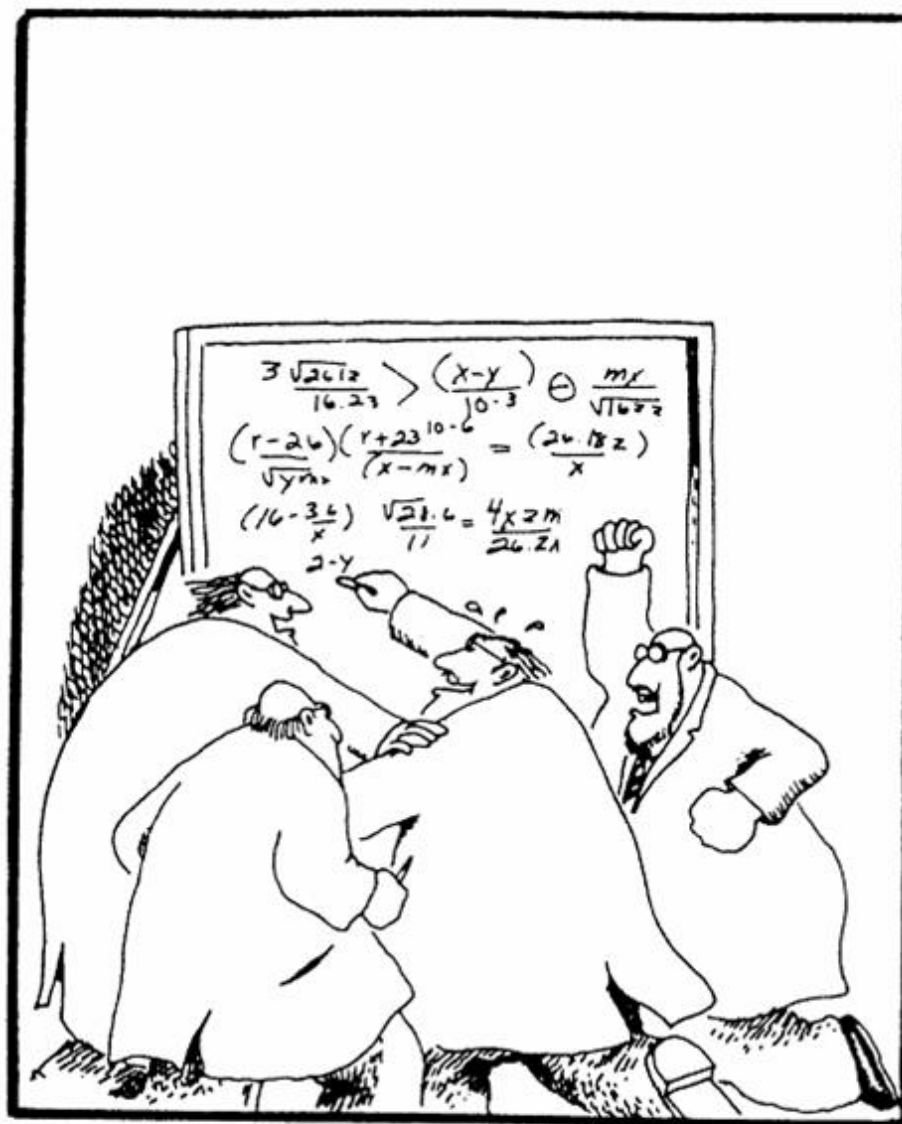
Akroyd: "Jane, you ignorant slut ..."

Curtin: "Dan, you pompous ass ..."

Saturday Night Live Weekend Update 1977-78

# Key elements of mediation

- Allow retreat with honor
- Reframe the disagreement to stress a common goal
  - protecting human subjects
  - facilitating ethical research
- ... then build consensus around that goal



"Go for it, Sidney! You've got it! You've got it! Good hands! Don't choke!"

# Meeting skills

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- leadership and time management
  - be prepared (and anticipate issues)
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  - encourage open and collaborative discussion
    - encourage alternative viewpoints (let people disagree)
    - encourage participation
- stay focused
  - redirect discussion to regulatory criteria for approval and underlying ethical principles
- resolve conflict and build consensus
- know the limitations of your expertise

# What do you need to be an IRB chair?

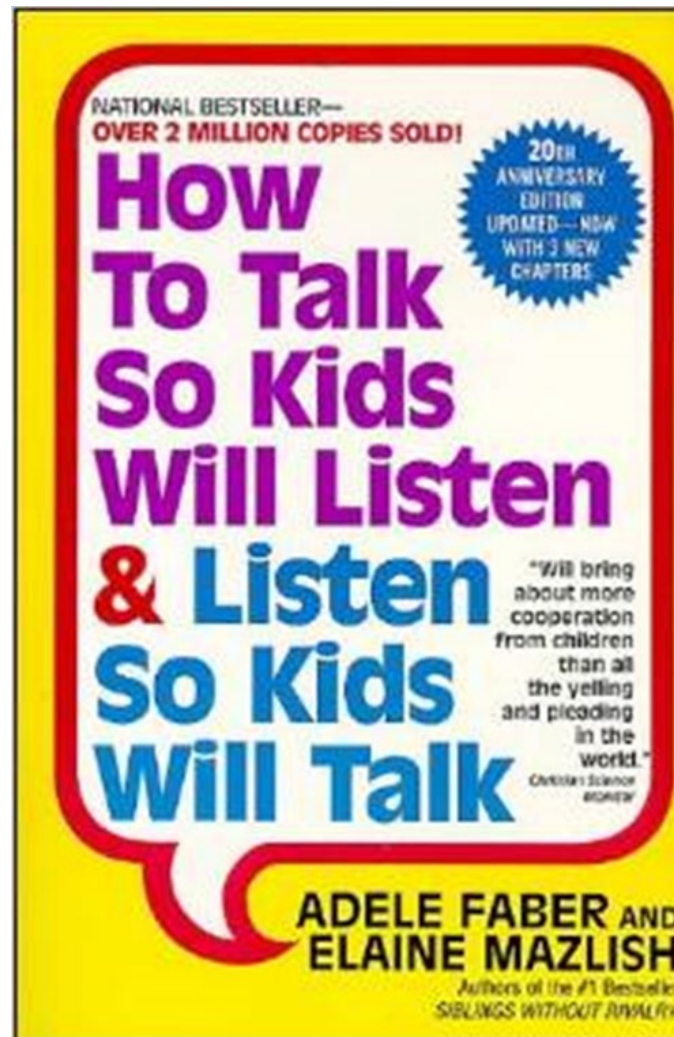
- meeting skills
- interpersonal skills
- knowledge

# Interpersonal skills

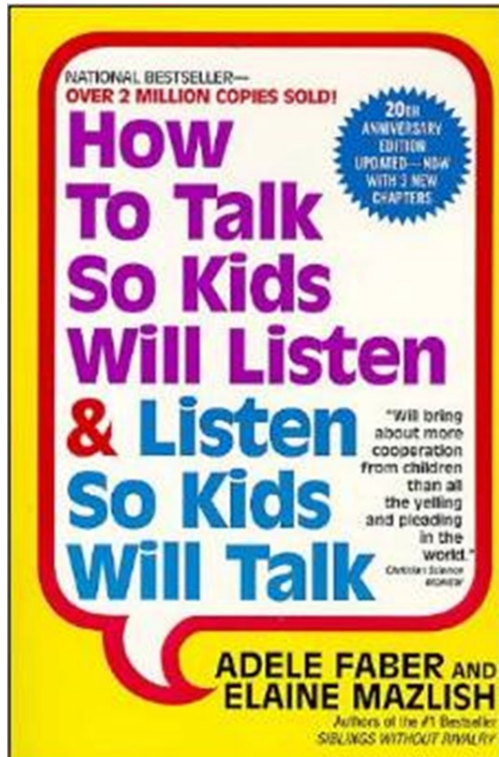
- role model for IRB membership
- ability to work with other components of the HRPP
- ability to work with investigators



# Working with investigators, or ...



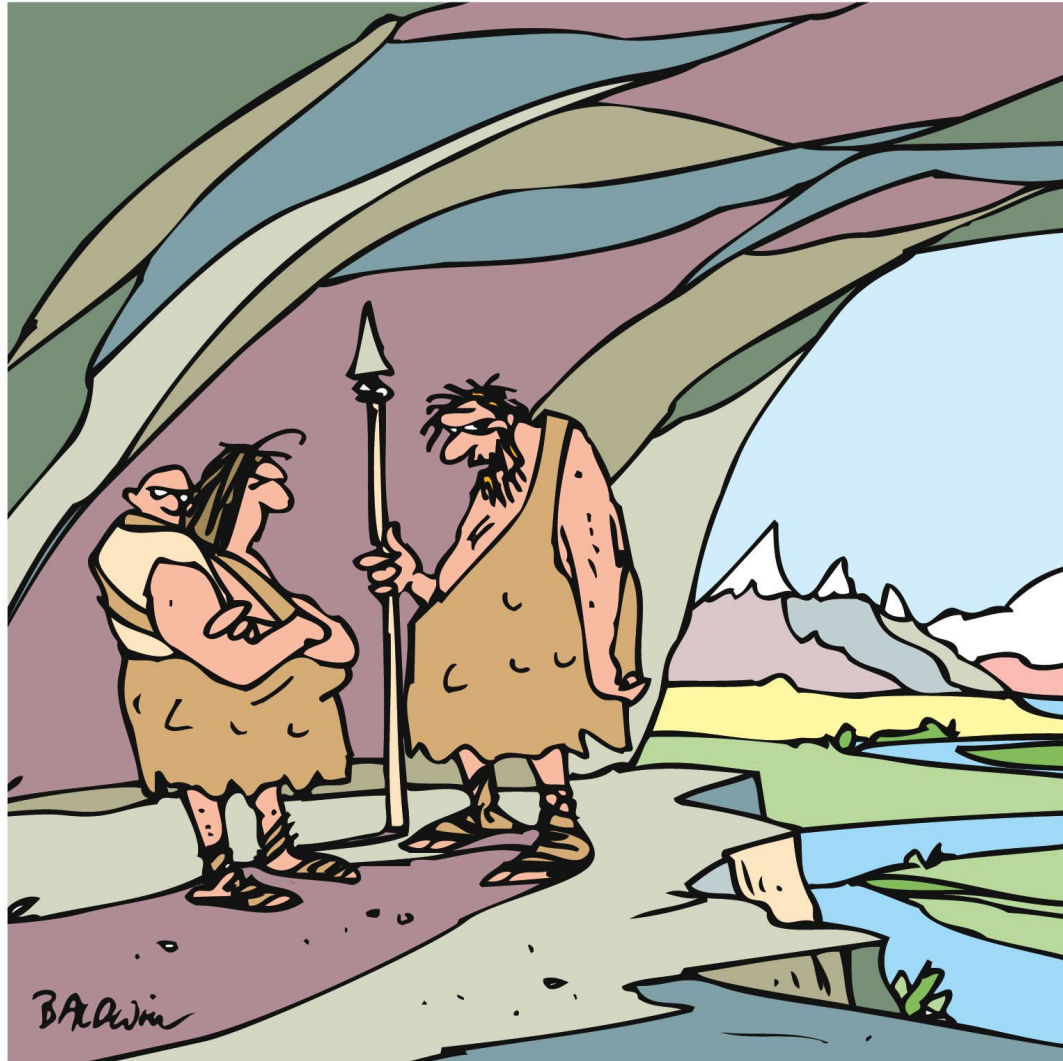
# How to talk so kids will listen ...



- Describe the problem ("So you want to ...")
- Instead of half-listening, listen with full attention
- Instead of questions and advice, just acknowledge
- Instead of denying the feeling, give the feeling a name ("That sounds frustrating")
- Give information instead of accusation ("That is wrong..." rather than "You did something wrong...")
- Avoid blaming, name calling, threats, moralizing, sarcasm

# Managing conflict

- Name the issues
  - Use neutral language
  - Avoid "you"
  - Separate interests and positions
    - "Position" is what each party is asking for
    - "Interests" are the underlying needs, desires, and goals
- Encourage a positive climate
  - Separate the people from the problem
- Allow retreat with honor
  - Reduce defensiveness
  - Avoid blaming



“I didn’t actually catch anything, but I do feel I gained some valuable experience.”

## Managing conflict

- A frustrated investigator whose protocol the IRB has just tabled (again) calls and "expresses his displeasure" (very loudly) ...

# Don't yell back



- De-escalation techniques
  - Lower your voice
  - Listen
  - Validate the other party's emotions
  - Don't argue
  - Postpone (suggest a time-out)

- He blames you for losing his funding, for not getting promoted, and for his failed marriage ...
- He concludes by suggesting that your parents weren't in fact married when you were conceived ...



# Don't take it personally



"I'm still evaluating the new truth serum, you micro-managing, pig-eyed, snot-nosed, burnt-out, impatient, obnoxious, penny-pinching, glory-hogging tyrant."

- Disruptive or aggressive behavior generally results from other life problems
- However, there is a limit to what verbal "abuse" you should take
  - Lower your voice
  - Postpone
  - Set ground rules for further conversation



"A little rudeness and disrespect can elevate a meaningless interaction to a battle of wills and add drama to an otherwise dull day."



Calvin and Hobbes  
(Bill Watterson)

# Be respectful



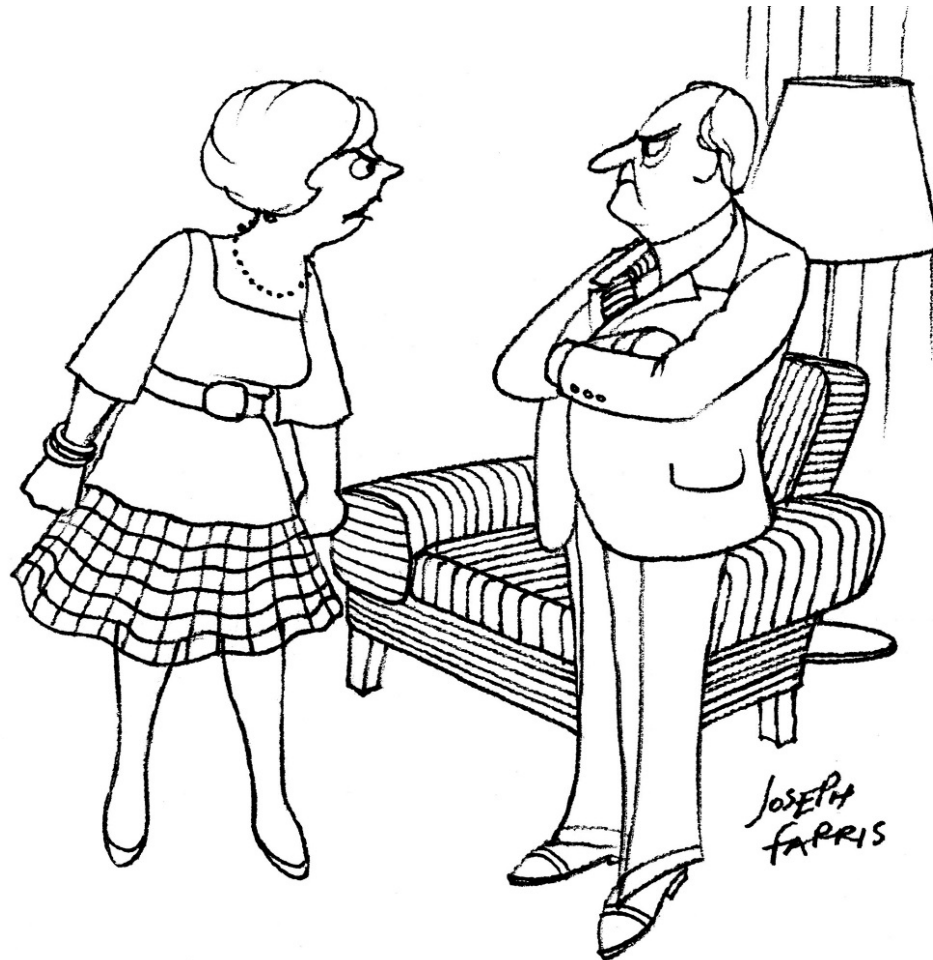
*"Mr. Dyer says he has no interest in speaking to anyone  
who would remain on hold for so long,"*

CartoonStock.com

- Respect: "a sense of the worth or excellence of a person, or a personal quality or ability ..."
- Respect does not necessarily mean agreement (or even amity)
- Respect is expressed by
  - listening carefully
  - acknowledging accomplishments of others

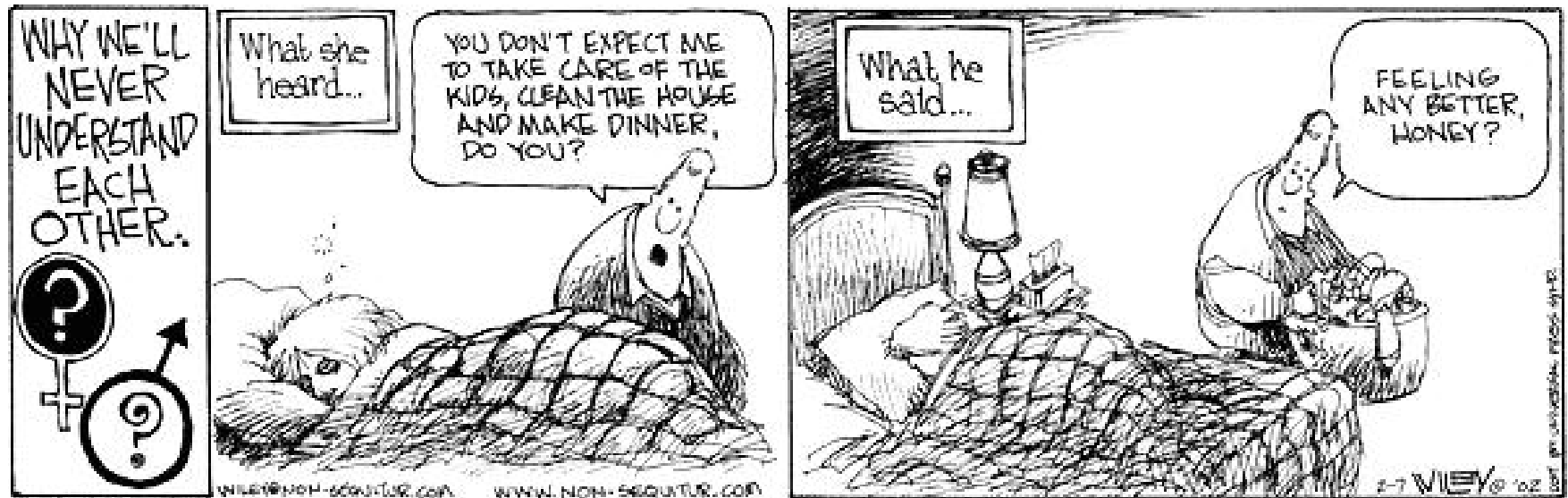
- PI (an anesthesiologist) wanted to get consent for a therapeutic study in the pre-op area, immediately before the operative procedure
- The IRB objected
  - One member remembered his recent surgery; he insisted that the pre-op area was noisy and busy and not conducive to thoughtful consideration and informed consent
  - Another member insisted the PI get consent during a pre-operative visit to the surgeon

# Be open-minded



"What's the point of looking at your side of the argument when it's wrong?"

# Listen



# Seek common ground

© Mike Baldwin/Cornered



“What’s important is that we found some common ground. Let’s try not to get bogged down over who found it first.”

- The investigator explained that he doesn't have an opportunity to meet the patients until right before the operation, that the pre-op area can be made quiet and private, and that patients have over an hour of "down time" (without interruption) during which the investigator can approach them
- We didn't understand the problem or the proposed solution until we asked and listened to the answer; then we were able to agree on an acceptable solution

CS424457



"HE DOESN'T SPEAK ENGLISH. ACT OUT FOR HIM THAT HE SHOULD TAKE 2 PILLS AND 3 PILLS ON ALTERNATE DAYS FOR NINE DAYS, AND THEN HE SHOULD COME BACK HERE."



- An investigator has a protocol allowing collection of extra tissue from various rare (and fascinating) cancers. He needs an emergency approval of a change in eligibility to allow enrollment of an incompetent subject whose LAR speaks only Bantu (and is also blind ...)
- Which is your response?
  - "An IRB may use the expedited review procedure to review ... **minor changes** in previously approved research" [45 CFR 46.110(b)], OR
  - "that's not the right thing to do ..."

# Don't blame the feds



DAVE COVERLY

"MISS WILCOX, SEND IN SOMEONE TO BLAME."

- An investigator comes to you and admits he can't find the last 5 signed consent forms ...

# Give them the benefit of the doubt

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# The New England Journal of Medicine

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Volume 258

FEBRUARY 27, 1958

## INFECTIOUS HEPATITIS\*

Studies of Its Natural History and Prevention

THE control of civilian population problems in preventing the etiologic agent or to tissue culture immunologic test solution of the present. Man susceptible host. The



# The New York Times

## *Syphilis Victims in U.S. Study Went Untreated for 40 Years*

ous doubts about the of the study, also say too late to treat the in any surviving ts.

s in the service say now rendering what- er medical services give to the survivors study of the disease's continues.

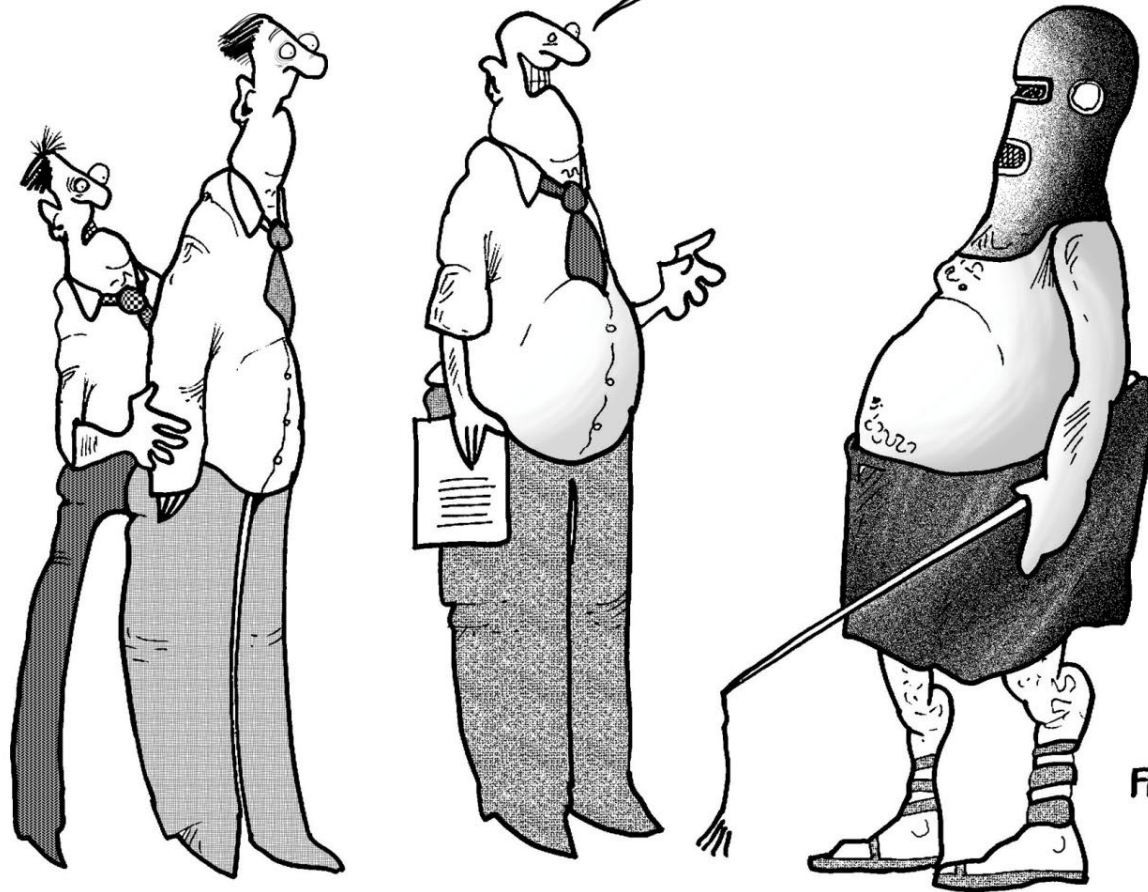
rlin K. DuVal, Assistant of Health, Education Welfare for Health entific Affairs, ex-shock on learning of r. He said that he was an immediate investi-

xperiment, called the Study, began in about 600 black men,



"IT APPEARS THE ETHICS COMMITTEE  
HAS GONE OVER THE EDGE."

AND THIS IS MR WHITTINGSTALL...  
HE'S IN CHARGE OF COMPLIANCE.



"Never attribute to malice what can just  
as easily be attributed to stupidity"

Malcolm Gordon  
circa 1975





*"Jerkins and I worked it out. He can have the office with the window."*

# what do you need to be an IRB chair?

- meeting skills
- interpersonal skills
- knowledge

# Knowledge

- Federal regulations
  - 45 CFR 46 (including subparts)
  - DoD, DoEd, DOJ
  - VA (38 CFR 16)
  - FDA (21 CFR 50, 56, 312, 812)
  - HIPAA (21 CFR 164)
  - FERPA?
  - GINA?
- State laws
  - subject protection
  - data privacy
  - informed consent
  - inclusion of vulnerable subjects
  - reproductive rights
- ICH-GCP
- GDPR?
- Institutional policies

# Knowledge

- know your limitations
- use your analysts and their technical expertise



"My job is to make decisions. Your job is to make them good decisions."

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# Knowledge



*“Fred, rumor has it you’re closing in on some profound, elemental truths about the universe, and I wanted to remind you that our research funding specifically prohibits that!”*

CartoonStock.com

- fundamentals (and challenges) of research
  - hypothesis generation
  - study design
  - recruitment
  - data analysis
  - statistical methodology
  - funding and other resources
  - publication

# Designing Clinical Research

FIFTH EDITION

COHORT STUDIES  
CASE-CONTROL STUDIES  
RANDOMIZED TRIALS  
DIAGNOSTIC TEST STUDIES  
SAMPLE SIZE  
INFORMED CONSENT  
COMMUNITY PARTICIPATION  
RECRUITMENT  
QUALITY CONTROL  
DATA MANAGEMENT

MEDICAL

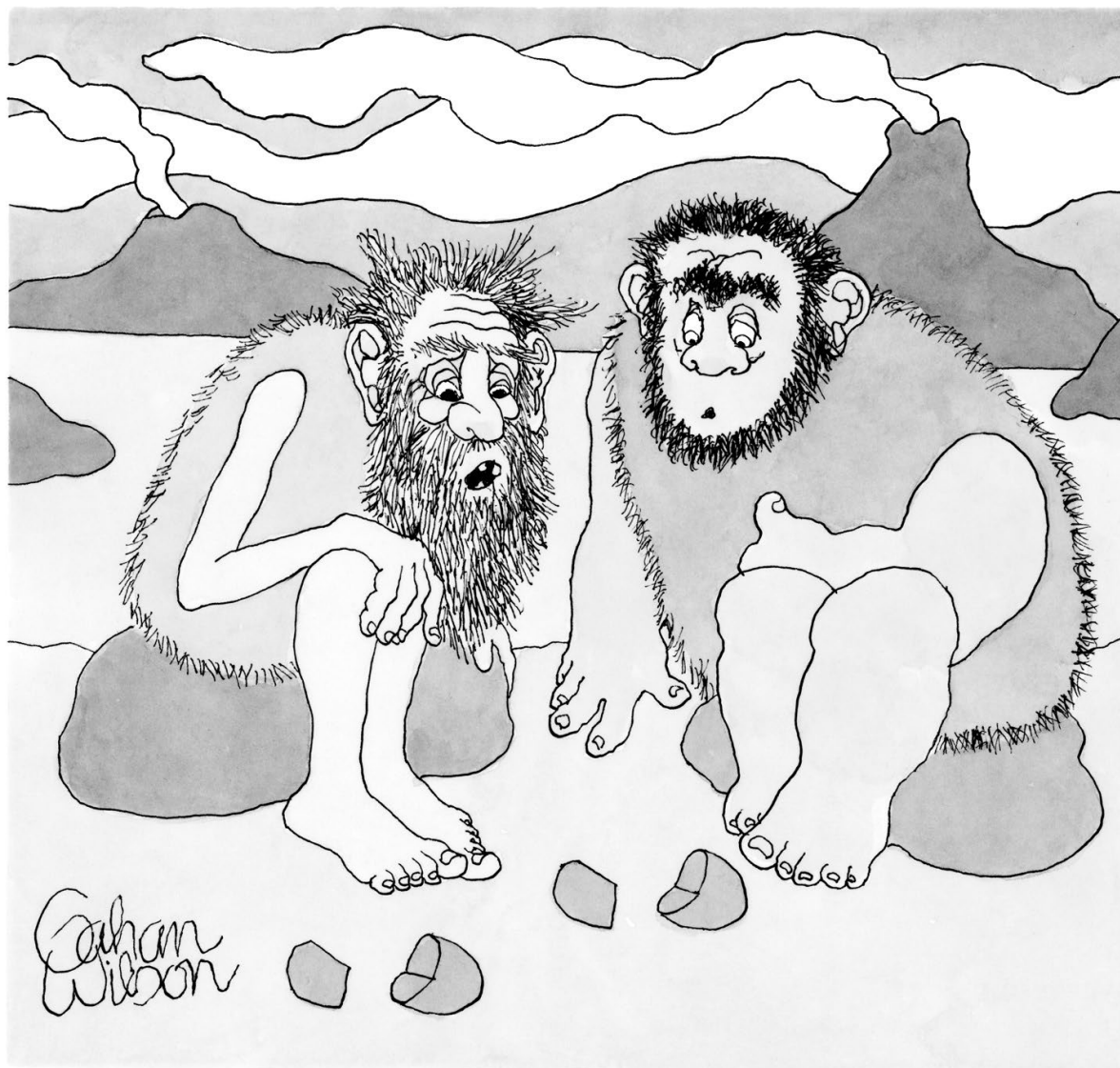
Warren S. Browner  
Thomas B. Newman

Steven R. Cummings  
Deborah G. Grady  
Alison J. Huang  
Alka M. Kanaya  
Mark J. Pletcher



Wolters Kluwer





*"There—now I've taught you everything I know about splitting rocks."*