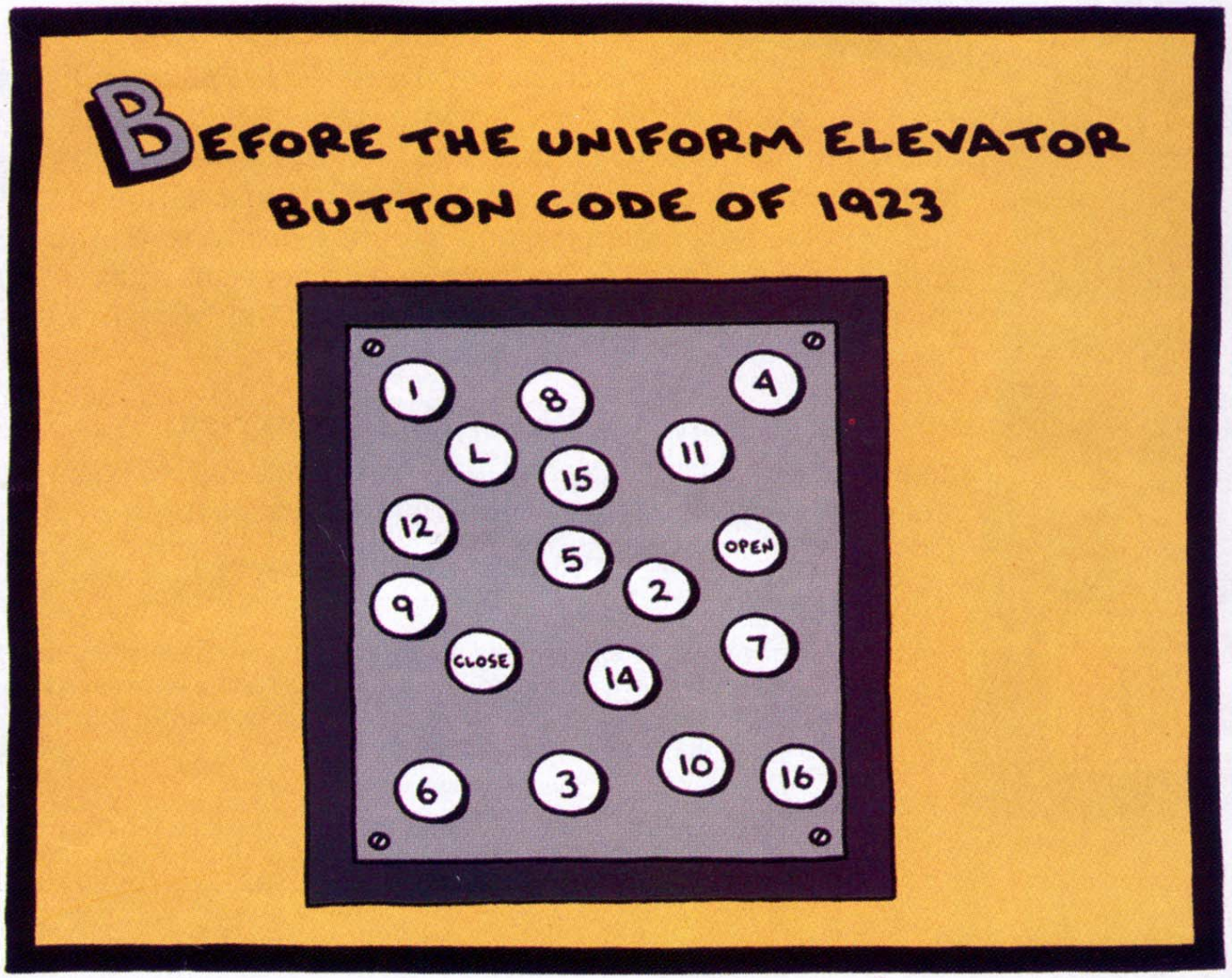
By A. J. Jacobs and Adam Green



# Are IRBs Efficient, Effective, or Redundant?

David C. Clark, Ph.D.
Director, Research Compliance
Rush University Center

# Efficient IRBs integrate their activities with...

- Senior Administration
- Research HIPAA Privacy policies
- Other local protection processes
- Conflict of Interest policies and Committee
- Clinical trial contract office
- Investigator clinical trial budgets

# Relationship with Senior Administration

- Reinforcement of IRB's value to the Institution
- Recognition for IRB service
- Sufficient expertise on the IRB
- Provision of adequate non-human resources
- Long-term planning with the IRB
- Collaborative problem-solving

# Integrating HIPAA Privacy concerns

- Criteria for “Waiver of Authorization”
- Criteria for “de-identification” of all data
- Accessing clinical information to recruit for clinical trials
- Re-use of data stored in data/tissue repositories

# Integrating other local protection processes

- Radiation Safety Committee (licensed by NRC)
- Radioactive Drug Research Committee (21 CFR 361.1)

- Institutional Biosafety Committee

# Integrating Conflict of Interest / Individual

- Institutional and IRB policies
- Ability to bring data about financial relationships to bear on specific studies in timely manner
- Communication between Conflict of Interest Committee and IRB

# Integrating Conflict of Interest / Institutional

- Institutional and IRB policies
- Ability to bring data about financial relationships to bear on specific studies in timely manner
- Communication between Conflict of Interest Committee and IRB

- Objectivity is more difficult

# Two relevant AAMC Reports

Protecting Subjects, Preserving Trust, Promoting Progress I: Policy and Guidelines for the Oversight of Individual Financial Interests in Human Subjects Research

- AAMC, December 2001
- Task Force on Financial Conflicts of Interest in Clinical Research

# Two relevant AAMC Reports

Protecting Subjects, Preserving Trust, Promoting Progress II: Principles and Recommendations for Oversight of an Institution's Financial Interests in Human Subjects Research

- AAMC, October 2002
- Task Force on Financial Conflicts of Interest in Clinical Research

# INFORMED CONSENT DOCUMENTS: Patient's responsibility for trial costs

- the following elements of information shall also be provided to each subject:

  (3) Any additional costs to the subject that may result from participation in the research.

(FDA) 21 CFR 50.25.b.3

# INFORMED CONSENT DOCUMENTS: Patient's responsibility for trial costs

- Should "costs to my insurance company" be considered "costs to me?"
  - I pay the insurance premiums
  - I pay the deductibles, co-pays, and remainders
  - My insurance expenses (today) sometimes limit my access to future insurance coverage
  - If my insurance doesn't pay, I could get stuck with a very large bill

# INFORMED CONSENT DOCUMENTS: Medical care for adverse consequences

- (Issue:) Does fault lie with product/participation or with Investigator?

- “Contract should contain prohibition against billing of patient’s insurer.”
- “Sponsors should not place dollar caps on medical treatment for adverse consequences.”

# INFORMED CONSENT DOCUMENTS:
## Patient's responsibility for trial costs

- "In no case should Sponsors require the Institution to bill the cost of subject's injury that is a consequence of trial participation to the subject's insurance company, then only pay for what is NOT covered by insurance."

- "Ethically unacceptable."

AAMC, January 2004

# New AAMC Report

## Clinical Trial Contracts: A Discussion of Four Selected Provisions

- AAMC, January 2004
- Baer, Feiler, Regulski, and Switzer

# INFORMED CONSENT DOCUMENTS: Patient's responsibility for trial costs

- Contract or practice that seeks to bill subject's insurance company (and requires documentation of "failure to pay") before Sponsor assumes any responsibility for expenses -- is this ethical?
  - Some patients pay via insurance premiums and co-pays while others do not -- is this equitable?
  - Means of including patients and providing clinical care to those who otherwise could not afford.