

Panel: Are IRBs Efficient, Effective or Redundant?

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IRB Mission

- The primary purpose of [IRB] review is to assure the protection of the rights and welfare of the human subjects.

21CFR56.102(g)

IRB Approval Criteria

- IRB determines the following:
 - 1,2) risks to subjects are minimized and reasonable
 - 3) selection of subjects is equitable
 - 4,5) informed consent is obtained and documented
 - 6) adequate monitoring of study data
 - 7) adequate privacy and confidentiality
 - 8) additional safeguards for vulnerable subjects

“Optional Extras”

- 50.24 rules
- HDE review
- Repositories/Banks
- COI reviews
- Subpart C reviews / reporting
- Exemption (46.101.b) determinations
- Adverse Event reporting / reviews
- HIPAA
- Contact Databases
- Scientific Review (lit)
- Certification*
- Accreditation*

“Let the IRB do it”



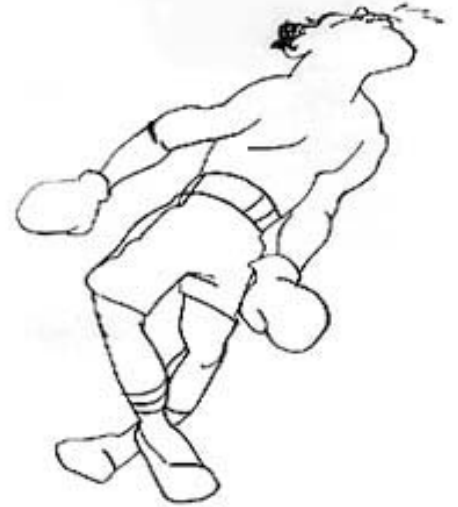
Why?

- Everyone is running scared
 - high-profile closures
 - law suits (institutions, PIs, IRBs)
 - sense of lack of ‘control’ (or ‘out of control’)
- Conservative interpretations
 - Federal regulators
 - Institutional offices (legal / risk management)
 - IRBs

“When in doubt – just say no.”

Stress

- Greater workload
 - do more, document more
- Less enjoyment / satisfaction
 - more staff / member turnover
- Has the level of Human Subject Protection changed for the better?



Reponses

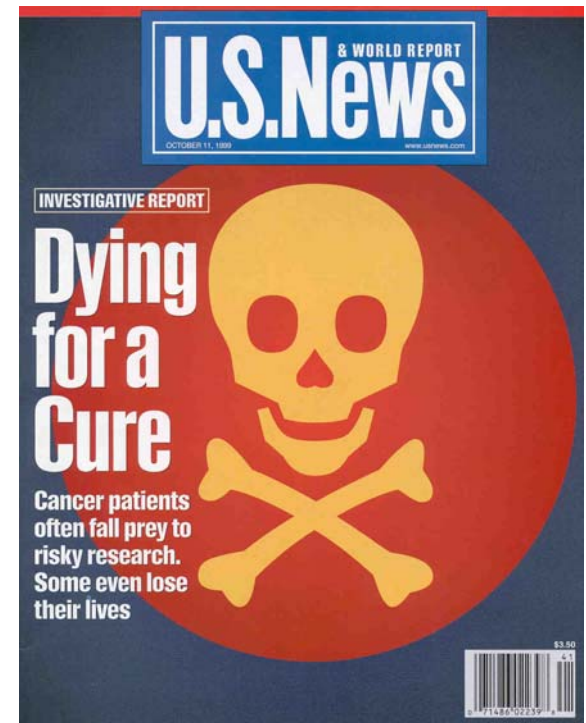
- Networking
 - ARENA membership / meetings
 - IRB Forum
 - IRBNet
- Electronic submission / review
- Central Review

Centralized Review

- Models
 - NCI
 - Contract IRB
 - Co-operative IRBs
- Cooperative Review (45CFR46.114)
 - Cooperative research projects are those projects covered by this policy which involve more than one institution. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy. With the approval of the Department or Agency head, an institution participating in a cooperative project may enter into a joint review arrangement, rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort.

Really Why?

- Trust
or, more correctly, lack of trust



Solution – System Change

- Return the concept of “trust” back to the system
- Accept that some will fail / abuse
- Focus on the outliers -
do not regulate / manage to the “1%”