
What Does an IRB do (and why)?

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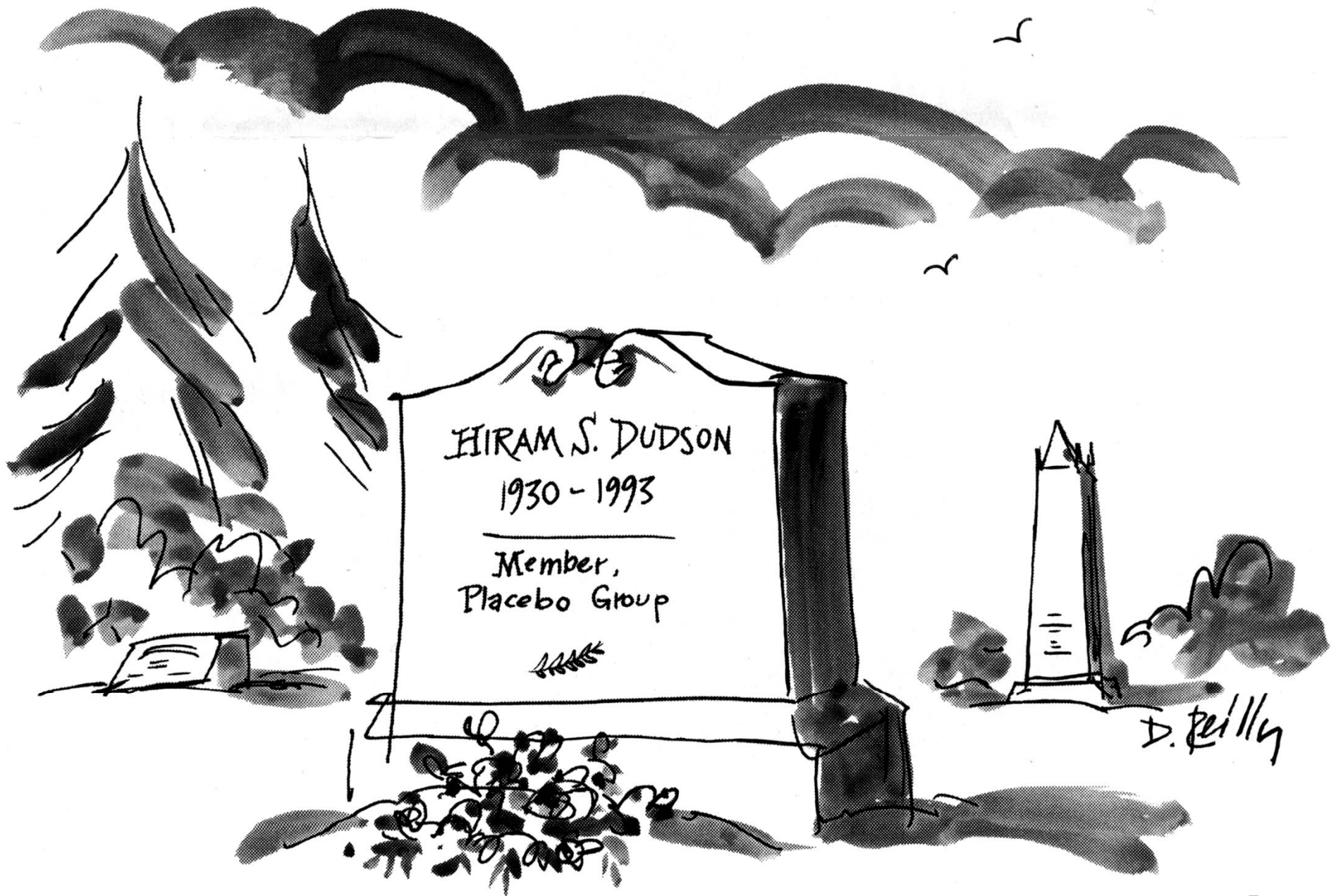


Financial Disclosures

- Berry Consultants, LLC
 - Multiple clients
- Support from
 - National Institutes of Health
 - NHLBI
 - NINDS
- Octapharma AG

Historical Perspective

- Historical abuse
 - World war II—multiple countries
 - Nuremberg Code (consent)
 - Declaration of Helsinki (independent review and sufficient scientific basis)
 - Tuskegee syphilis study (ongoing information)
- Belmont Report
 - Basic Ethical Principles
 - Respect for Persons
 - Beneficence (vs. non-maleficence)
 - Justice



“Common Rule”-- 45 CFR 46

- §46.101 To what does this policy apply?
 - “...all research involving human subjects conducted, supported or otherwise subject to regulation by any federal department...”
- §46.102 Definitions
 - Research (activity “designed to...contribute to generalizable knowledge”)
 - Human subject (an identified “living individual”)
- §46.103 Assuring compliance
 - Institutional Review Board (IRB)

45 CFR 46 (continued)

- §46.107 IRB membership
 - “...IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities...”
- §46.109 IRB review of research
 - Review research
 - Review consent form and consent procedures
 - Continuing review

45 CFR 46 (continued)

- §46.110 Expedited review procedures
 - <http://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html>
 - Minimal risk research (§46.102i)
 - “Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.”
 - Minor changes in previously approved study

What do They Talk About?



45 CFR 46 (continued)

- §46.111 Criteria for IRB approval
 - Risks are minimized (B)
 - Risks are reasonable relative to expected benefits and knowledge to be gained (B)
 - Selection of subjects is equitable (J)
 - Informed consent (RfP)
 - Subject
 - Legally authorized representative
 - Emergency exception (e.g., 21 CFR §50.24)
 - Documentation of informed consent (RfP)
 - Monitoring of study data (B)
 - Privacy and confidentiality of data (RfP)
 - Protection of vulnerable populations/no coercion (RfP)

45 CFR 46 (continued)

- §46.116 General requirements for informed consent
- §46.117 Documentation of informed consent

45 CFR 46 Subpart D: Children

- §46.404 Research not involving greater than minimal risk
- §46.405 Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects
- §46.406 Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition
- §46.407 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children
- §46.408 Requirements for permission by parents or guardians and for assent by children



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Centralized IRBs

- Goal is to leverage repeated experience with protocol or disease to increase efficiency and consistency
- National Institutes of Health (NIH) Policy on the Use of a Single Institutional Review Board of Record (but single \neq central)
- Most useful in initial approval, less so for ongoing monitoring
- Unlikely to fully appreciate local considerations
- Vary tremendously in quality and cost



Common Rule 45 CFR 46 is in Flux

- “Old Rule”
 - Common Rule published in 1991
 - Currently in effect
- “Revised Common Rule”
 - Published in 2017 and revised in 2018 but not implemented
 - Currently in a “delay period:” July 19, 2018 through January 20, 2019, with requirements becoming effective January 2019
 - There are three burden-reducing provisions of the new rule that can be used now

Common Rule 45 CFR 46 is in Flux

- There are three burden-reducing provisions of the new rule that can be used now
- Those three provisions are:
 - The revised definition of “research,” which deems certain activities not to be research covered by the Common Rule;
 - the elimination of the requirement for annual continuing review with respect to certain categories of research;
 - and the elimination of the requirement that institutional review boards (IRBs) review grant applications or other funding proposals related to the research.

Conclusions

- Successful interaction and partnership with your IRB depends on
 - Understanding the IRB
 - Purpose and role
 - Composition
 - Regulatory requirements
 - Building trust and mutual respect
 - Prepare IRB applications with the same care you'd prepare a manuscript or grant application
 - Following policies and procedures