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Evolving roles of statistics at National Heart, Lung and Blood Institute

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History

- Harold Dorn came to the NIH in 1946 and hired a group of statisticians who shared an office on the NIH campus:



Jerry Cornfield; Jack Leiberan; Nathan Mantel;
Marvin Schneiderman; Sam Greenhouse

- His vision “was to provide the best statistical advice in response to questions posed by intramural scientists, epidemiologists and other non-laboratory investigators”, and “to conduct statistical research in theory and methodology (without limitation)”.

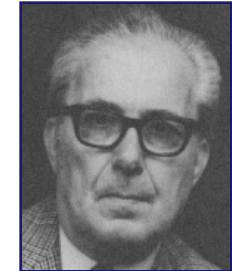
OBR Leadership at NHLBI

- **Jerry Cornfield: 1963 - 1967**



Worked in many areas (epidemiology, carcinogens, smoking, cardiovascular disease, diabetes) . Known for his contributions to the nature of clinical trials, Bayesian inference, and the relationship between statistical theory and practice.

- **Max Halperin: 1968 - 1977**



Directed a program of research related to clinical trials with intellectual fervor, brilliance and generosity. Strongly influenced the design of seminal trials in heart disease.

OBR Leadership at NHLBI (continued)

- **David DeMets: 1977 - 1982**



- **Janet Wittes: 1982 - 1990**



- **Nancy Geller: 1990 - date**



Today, as an extramural research unit, the OBR has three missions:

- First, it fulfills a variety of roles in the planning, design, implementation and analysis of NHLBI studies which are supported by contracts or cooperative agreements.**
- Second, the staff has research interests in new statistical methodology for clinical trials and publishes actively in the biostatistical and statistical literature.**
- Third, the group serves as consultants to any NHLBI investigator with statistical questions.**

Some OBR achievements

- Organizational structure for multicenter clinical trials
- Design considerations related to patient risk, non-compliance, a lag in treatment effect and use of intention to treat analyses
- Methods for sequential analysis of accumulating data (Lan-DeMets use functions, conditional power, non-symmetric bounds for monitoring)
- New methodology for longitudinal data with informative drop out stimulated by epidemiological studies.
- Internal pilot studies and adaptive clinical trial design
- Survival analysis (sample size, non-proportional hazards)
- Multiplicity issues (multiple endpoints, multiple comparisons, monitoring)

OBR Today

- **12 PhD statisticians (including OBR Director, Dr. Nancy Geller)**
 - Collaborate in the design and analyses of studies funded by NHLBI
 - Consult with any NHLBI investigator needing statistical advice
 - Collaborate in data management and analysis of some studies sponsored by the Division of Intramural Research

- **Conduct statistical research with interests include:**
 - Clinical research studies, including efficient designs for clinical trials
 - Longitudinal data analysis
 - Mid-trial corrections
 - Statistical genetics and genetic epidemiology
 - Survival analysis

- **Mentoring summer interns and undergraduate research**

