

62-RPO-DJV
DHS - Letters & memoranda

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DEPARTMENT OF PUBLIC WELFARE

To: Superintendents
ATTENTION: Medical, Research Staffs
Mental Health Medical Policy Committee

March 27, 1962

From: David J. Vail, M. D.
Medical Director

Subject: Research policies

The following is an excerpt from my talk to the Research Conference on February 26, 1962. I thought it might be useful to you as a general summary of policies on research administration and procedures.

"Mental Health Research in Minnesota"

"Our laws provide for an advisory committee of five medical and basic science specialists entrusted with establishment of general policies. They advise on the distribution of State research monies and 'guidance' of research. We have interpreted the latter to mean all research whether involving State money or not. A staff coordinator supervises the overall management of the research program.

"We desire to strike a balance between project research -- the piecemeal approach -- and program research, whereby regular yearly grants are made from a central fund to an operational unit, in this case the research department of various state hospitals. The preference is for the latter. The program approach, however, if not properly disciplined, can foster the inertia and other faults already commented on. There must be a suitable balance between requirements and permissiveness.

"The program request should set forth broad guidelines for the period in question. The subsequent performance should bear some resemblance to the plan, although with wide flexibility. About a 50% correspondence seems reasonable. The basic program must be approved by the advisory committee.

"Subsequent clearances may be required. Here it is important not to overburden the researchers with too much procedure; it was precisely for this reason that the project approach was abandoned in favor of the program approach. Judgment on the part of the researcher and the state-level director are required. Under certain conditions, for example in experimental drug research, bits or segments of the overall program should be cleared as the work proceeds. This is because of the serious implications of drug research, discussed more fully below. Deviations from or additions to the basic program should be cleared, especially if they may involve some major changes within the hospital or raise the 'guinea pig' issue. Example: Moving a large number of patients into a special research ward.

"For a combination of legal and policy reasons applications for outside funds, federal or private, must be cleared.

"The method of clearance may be by informal written or conversational means, by consultation with a small subcommittee empowered with interim authority, or by formal review before the full committee. Sometimes approval may be obtained retroactively, but our experience is that the committee does not enjoy being compromised or forced into a rubber stamp position in this fashion.

"Drug Research

"No area of research enterprise in the public setting arouses such thorny problems as research on drugs. This is exaggerated by the intensive output of new compounds by the drug companies and complicated by public controversies such as those raised in the Kefauver hearings. In drug research are crystallized the two most critical issues of research in a state hospital system: (1) money and how it is handled, and (2) experimentation on a population who are wards of the state and whose ability to give consent may be questionable -- the 'guinea pig' problem.

"A related issue is that of the reputation of the hospital or of individual physicians. There appear to be some groups or individuals who can be relied on to produce favorable evaluations on drugs, and the pharmaceutical houses are quick to discover them.

"1. Experimental vs. established drugs.

"FDA-approved and marketed drugs are no particular problem here. There is always a tendency to drift into 'open bottle' studies or poorly structured research designs. Such research is of a low level. It may, however, have a stimulating effect on medical and other staff. Assuming that the drug is safe, the dangers that remain are those of inconclusiveness and wasted effort, and the possible damage to reputation that may ensue.

"Experimental drugs are quite a different matter. We have become increasingly strict about these, and our practice now is to refer all such requests for evaluation to a large federally-supported project centered at the University of Minnesota, where suitable animal and laboratory checks can be made.

"2. Handling of money.

"Because of all the administrative and ethical implications we have established these two policies related to reimbursement from private sources for research:

- (a) All payment must be handled through the State Treasury and other official channels, and not directly or unilaterally.

- (b) There should be no remuneration to the professional staff conducting the research. Clinical and ward personnel who work overtime on the research are properly entitled to recompense and naturally will participate better if this is done.

"As to goals, we encourage publications and presentations in every possible way. We have avoided any arbitrary standard and the 'publish or perish' pressure system. At the same time we stimulate at every opportunity and publish a list once each year. 'Publication' means a recognized professional or scientific journal. We do not count mimeographed or other self-published articles. Nor do we count items 'submitted for publication.' 'Presentation' means participation in the program of a major national or regional meeting of a professional or scientific society. We would not count political undertakings such as the council or executive committee of the organization, nor an organization so esoteric and limited in membership that participation in the program is meaningless. Presentation at state meetings and especially those of the state mental health system itself do not count.

"Lastly, we are attempting to work out an incentive system for providing an increase in travel funds so that those who do participate in scientific programs in the manner described will be better able to attend."

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