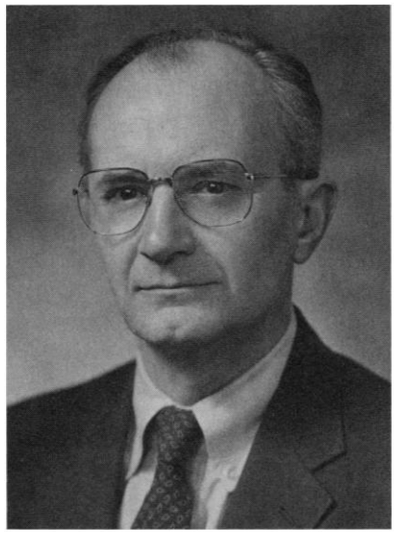
Stanford, Claiming Censorship, Sues NIH

A dispute over a clause in a research contract has escalated to a legal battle between Stanford University and the National Institutes of Health. The issue: who should control the release of information from research projects that involve several different research groups?

The dispute began on 19 June, when the National Heart, Lung, and Blood Institute (NHLBI) gave Stanford University a $1.5-million contract so that cardiac surgeon Philip Oyer could test a totally implantable heart device in patients waiting for a new human heart. Made by Novacor, the device is described as "being as small and unobtrusive as possible, in an attempt to provide an acceptable quality of life for the patient."

When Stanford signed the contract and sent it back 9 days later, it included one proviso. The university objected to a "confidentiality" clause stipulating that no data from the trial could be released without the prior approval of the contracting officer at NHLBI headquarters in Bethesda. The offending clause says: "Written advance notice of at least 45 days will be provided to the Contracting Officer of the Contractor's intent to release findings of studies or research which have the possibility of adverse effects on the public or the Federal agency. If the Contracting Officer does not pose any objections in writing within the 45-day period, the Contractor may proceed with disclosure."



No precedent. *Heart institute head Lenfant says the clause is not unusual.*

Stanford said the clause had to go, claiming that it violated university policy regarding freedom to publish—not to mention the First Amendment guarantee of free speech. The right to publish freely, says Stanford medical dean David Korn, is "an extremely important issue of federal science policy and is terribly troublesome."

To the assertion that the confidentiality clause amounts to a violation of free speech, NHLBI director Claude Lenfant in effect said nonsense. In a letter to Stanford president Donald Kennedy, Lenfant noted that the clause is frequently incorporated in contracts for multicenter clinical trials (in this case a second identical contract went to the University of Pittsburgh) in order to assure that publication represents the "collective judgment" of the collaborators. Lenfant pointed out that, in practice, decisions about the release of data are made by a publications committee (not the contract officer) on which Stanford would be represented. And, Lenfant added, "Stanford University has already performed directed research under Institute contracts that have included the clause."

Kennedy shot back a letter saying that those past cases "were simply the result of administrative error [on Stanford's part]." He reiterated his argument that the language of the confidentiality clause, while laudable in intent, was nonetheless so restrictive as to give NHLBI the powers of censorship. And Kennedy proposed a solution: rewrite the contract to ensure collaborative publication without granting absolute authority to a federal official and eliminate the vague phrase about "adverse effects" on a federal agency.

But Lenfant would not budge. He told *Science* that "We couldn't change our policy just for Stanford." On 31 August, Lenfant decided enough was enough. He told Kennedy that NHLBI was withdrawing its offer to award the contract. It went to St. Louis University Medical Center in Missouri instead.

Apparently Kennedy also had had enough. On 24 October, Stanford filed suit against the National Institutes of Health. In papers filed in federal court for the District of Columbia, Stanford claims that the heart institute's actions were "arbitrary, capricious, and an abuse of discretion" serious enough to make the contract withdrawal illegal.

In court papers, Stanford takes issue with each of the grounds on which NIH says the clause is justified. First, to NIH's statement that the confidentiality clause protects the privacy of patients and prevents premature release of proprietary information, Stanford replies that other, existing provisions guarantee patient privacy and that there is no proprietary information to worry about in this particular case. Second, it contests NIH's assertion that the clause protects the public because "public disclosure of preliminary unvalidated findings could create erroneous conclusions which might threaten public health or safety if acted upon." That, Stanford says, is hardly pertinent since the implantable assist device "could certainly not be obtained...by the general public." Stanford surgeon Oyer, who has been working on implantable heart devices since 1973, says it is "bizarre that anyone could think premature disclosure of results could hurt public health or safety."

Stanford is demanding its contract back. But St. Louis and Pittsburgh have accepted the contract, which includes the disputed confidentiality clause. Surgeons at the two institutions are in the initial stages of designing a joint protocol for implanting a left ventricular assist device in up to ten patients at each university hospital. In fact, no matter what the outcome of the dispute, any human trials of the assist device are at least a year away, more likely longer. Oyer, who has been working with Novacor for years, is doing the animal trials that must precede any human surgery and those animal tests—in sheep—won't start until January. Says Oyer, "If everything goes perfectly, we'll have the data in a year." Then the data go to the Food and Drug Administration for its approval before surgeons anywhere can put the device in patients.

In a telephone interview with *Science*, David Lagunoff, research director at St. Louis, said: "We don't see the NIH as a great threat to scientific publishing. And we buy the idea that there have to be some limits in a collaborative study. Perhaps the wording could be a little different," he concedes. But, Lagunoff says, "The real issue here is the orderly presentation of scientific results in a collaboration. You can't have one group publishing on its own." In principle, Stanford agrees. It just can't live with the wording of the offending clause.

So, Stanford and NIH will slug it out in federal court.

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