

## Informed Consent Challenged

## Drug Tests Stir Debate on Ethics

By Bill Richards

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As military documents go, the Army's Volunteer Participation Agreement, signed by the thousands who took part in the Army's 20-year program of drug and chemical experiments, is unusually simple and direct.

"I recognize," the three-paragraph form reads, "that in the pursuit of certain experiments transitory discomfiture may occur and when such reactions seem especially likely to occur I will be so advised."

The only hint that more than transitory discomfiture might be involved is a request for the name, address and telephone number of the volunteer's next of kin.

Her reports that at least some of the 585 volunteers given LSD and nearly 2,500 others who were given other hallucinogens experienced serious side and after effects said never really understood what they were doing, the Army quietly scrapped its old release form last month.

The Army has instituted a new release form," announced a spokesman last week at Edgewood Arsenal, where the experiments were headquartered, "because they felt the old one wasn't specific enough."

But the Army's use of the old form to clear the way for nearly two decades of military experimentation without any outside regulation has spurred inquiries by several congressmen and at least two federal agencies into the program.

Even more significant, perhaps, is the intensity that

the latest revelations have added to the controversy over the ethics of medical experimentation with the so-called "informed consent" of the person who signs a release form.

The Army and Dr. Van M. Sim, who was until recently head of the medical research program at Edgewood, have publicly maintained that the experimentation is in the interest of national defense and that to tell persons involved in them more than the vaguest of detail would skew the results.

In addition, Army spokesmen have recently emphasized that all those in the program were volunteers and all signed the release form—although the spokesmen could only say that the volunteers were supposed to have been told there could be aftereffects from the experiments.

"Signing a piece of paper is not of consequence," said Alex Capron, associate professor of law at the University of Pennsylvania Law School and co-author of a legal casebook on the legalities of medical experimentation.

"Consent is the whole process of informing fully, answering questions and then permitting the person time to fully think it over before making his decision."

The major controversy surrounding informed consent, Capron said, is whether individual doctors performing research experiments on humans should determine how much a subject should be told in advance or whether the matter should

be decided in advance by law.

There is no federal law on the subject, he said. Instead each state sets its own rules. In 1973 the District, California and Rhode Island all ruled that a legal standard should determine informed consent. About a dozen states have thus far adopted similar procedures, Capron said.

Capron, like some others in the recently expanded field of medical research law, advocates requiring a potential medical research subject to describe in full his own version of the coming experiment and the risks involved. "If he doesn't know then he shouldn't be involved," Capron said.

In the case of the Army, Capron pointed out that the manpower pool of potential volunteers was large enough to allow for additional tests to determine what effect fully informing research subjects would have on the results of the tests.

"It is usually possible to design an experiment to allow for fully informing the subjects, yet still obtaining usable experimental data," he said. "It is unfair to take humans and tell them you're going to make the decision for them as though they were guinea pigs."

The term guinea pig is enough to make almost anyone connected with the Army experiments wince. "We knew what we were getting for volunteers because he screened the hell out of them," said Sim.

Persons involved in the tests were told to write the Edgewood researchers if

they thought they were having any problems because of the tests. Only seven did write before the recent publicity, Sim said, and several of those never did get LSD during the tests.

But, according to a number of persons who took part in the testing the suggestion to write was as vague as the consent form. "I just didn't know what was happening to me and nobody ever told me anything would happen," said an Air Force veteran who went through long periods of deep depression after taking part in the LSD tests.

Another former Army officer who as given LSD and then discovered what he believed were aftereffects said he received no help and was actually discouraged by military officials at Edgewood when he suggested there might be similar problems with others.

Moreover, the Army admitted that it placed restrictions on servicemen who took part in the tests about mentioning them and did not put notification of their participation in their files which were the most likely to be examined if problems did occur.

despite the fact that the Army, and to a lesser extent the Navy, Air Force and CIA did conduct or fund LSD research from the early 1950s there was almost no outside regulation.

The Federal Food, Drug and Cosmetic Act, passed in 1938 and sharply tightened in 1962 after the disaster with the experimental Thallomide drugs in Europe and England, required close supervision of drug tests by the Food and Drug Administration.

But a memorandum signed by the EDA in 1964 and reaffirmed in 1974 allowed the military virtual total responsibility for its own testing procedures, according to FDA sources.

The memo, according to

the sources, states in part, "The Department of Defense assumes full responsibility for the protection of all human subjects involved in research under its sponsorship whether this involves investigational drugs or other hazards."

The sources said FDA officials and the General Accounting Office have both launched quiet inquiries into military use of drugs since reports about the LSD experiments were published last month.

"What we are looking into is just how much was known by the so-called volunteers when they were given drugs like LSD," said an FDA attorney. "If they didn't know what they were getting and the Army deceived them then I'd say the ethics of that are zilch."

FDA officials are also looking into the Army's tests with the super-potent long-term hallucinogen known as BZ. "It is something most of us never heard of before this," said the FDA attorney. "The fact that it was being widely tested means it may have been available to the street drug trade and we'd like to know whether the Army gave information about its experiments to the Justice Department."

Dr. Judd Marmor, chairman of the American Psychiatric Association, said in an interview last week that he believed some of the government experimentation with LSD may have been wrong.

"The fact that the CIA gave drugs secretly and without the subjects' knowledge I feel is highly unethical," he said. According to the Rockefeller Commission report on CIA activities the intelligence agency tested LSD on unsuspecting persons between 1953 and 1963 and continued its LSD tests on volunteers until 1967.

The Army's drug testing, said Marmor, who has tested LSD himself on cancer patients in Los Angeles, is more difficult to condemn.

"The problem of informed consent is a little tricky," he said. "If you tell every possible result you may lose your volunteers. There's a fine line between what is ethically necessary and that which may preclude valuable research."

"Where the Army fell short," said Marmor, "was that once they learned something about the effects of LSD they had an ethical obligation to make sure the volunteers were all right."

Until 1973 the Army followed up on only two of the 1,500 military and civilian volunteers, Sim said last week. It is beginning a program of tracing and giving mental and physical examinations to all who took part in the tests.