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HEADLINE: UC drops controversial psychoses tests

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Critics contend studies unethical

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The Cincinnati Enquirer

Complaints by advocates for the mentally ill, locally and nationally, have prompted the **University of Cincinnati** to drop its most controversial psychiatric research studies.

The announcement Wednesday comes as federal investigators are examining research practices at UC and Cincinnati's VA Medical Center, which are affiliated.

Known as "challenge" studies, the research involves giving people chemicals that may induce psychosis to study its biology or to test a treatment.

The study that raised concern locally was a 1997 clinical trial at UC in which 13 patients who were delusional or hallucinating for the first time were asked to take amphetamines, which are known to worsen symptoms in many cases.

Critics complained that people with psychoses severe enough to warrant hospitalization were denied treatment for their illnesses for five days just to complete the study.

Dr. Randy Hillard, head of the Department of Psychiatry at UC, said the amphetamine study was conducted with adequate safety measures. But he said that no more challenge studies will be undertaken by his department until critics are satisfied.

"Nationwide, there is enough of a question about (the studies) that we will stop doing them until there is a consensus about how they should be done," Dr. Hillard said.

His comments came Wednesday afternoon after a meeting with four Cincinnati-area advocates for the mentally ill:

Mike Fontana, president of the Mental Health Association.

James Coleman, coordinator of Recovery Initiative.

Urban Waldbillig and Fred Zimmerman, both of Consumer Network.

"Those guys in Cincinnati, they're making history," said Vera Hassner Sharav, founder of Citizens for Responsible Care in Psychiatry and Research, a New York-based group of families with sons and daughters who suffer from schizophrenia.

She said the agreement between advocates and UC, which was still being written late Wednesday, could serve as a national model.

"It does recognize finally the right of the community to be in the process of evaluating and approving research on human beings," Ms. Sharav said.

In addition to ceasing challenge studies, UC has proposed creating a committee of mental health consumers, family members and researchers.

One job of the committee will be to look at proposed research. Any high-risk or nontherapeutic studies that raise objections can be brought to UC's Institutional Review Board (IRB), a 22-member commission that oversees all medical research at the university, the VA and Shriners Burns Institute.

"Things are going our way," Mr. Coleman said Wednesday. "There are some other unresolved issues, but there is a major difference. Now we have a right to present our case to the IRB."

Dr. Hillard said he hopes to set new national standards, including the addition of an outside professional to decide whether study participants are capable of giving informed consent.

Cincinnati is one of dozens of communities discussing changes to human research, especially in psychiatry.

In January, the National Bioethics Advisory Commission issued 21 recommendations for change in psychiatric research. The commission heard 18 months of testimony from former research subjects, their families, scientists and members of the public.

At the same time, the Office for Protection from Research Risks (OPRR), an arm of the National Institutes of Health, has been investigating UC for two years. It extended the investigation to Cincinnati's VA early last month.

An initial finding by OPRR is that the IRB must re-review all of its federally funded medical research, at least 98 studies.

Critics say challenge studies are inherently unethical because they deliberately aggravate a health problem.

"How can a physician, whose first obligation is to do no harm, make someone psychotic?" asked Leonard Glantz, a professor of health law at Boston University School of Public Health. "It's like saying, 'Let's give someone a heart attack and see what's going on.' "

Even worse, the 1997 study sought out newly diagnosed patients for challenge

studies.

"To take a first-time delusional (patient), then give them an amphetamine to make it worse . . . we're against that totally," Mr. Coleman said. "They'll say legally they're allowed to do it. But we think ethically that it's wrong."

But Paul Appelbaum, vice president-elect of the American Psychiatric Association, said that challenge studies raise questions from the public because they do not seem to have a direct benefit for the sick. A new drug's benefits are clearer.

"The hope is in the long run enough pieces of knowledge will be accumulated that it can help patients," said Dr. Appelbaum, head of the psychiatry department at the University of Massachusetts Medical School.

Dr. Hillard said he is willing to forgo that payoff for the time being.

"We know how things have been done in the past, and it has led to some amazing discoveries, but are there other ways to accomplish the same thing?" he said. "I hope what comes out of this is a collaboration" with the mentally ill.