

UNC-CH wins \$42.1 million federal contract to study drugs for schizophrenia and Alzheimer's

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CHAPEL HILL – The University of North Carolina at Chapel Hill has won a \$42.1 million federal contract to determine the effectiveness and safety of a new class of anti-psychotic drugs for treating people with schizophrenia and those with psychotic and disruptive behaviors associated with Alzheimer's disease.

The contract, announced today by the National Institute of Mental Health (NIMH) in Bethesda, Md., is the largest ever awarded by the federal agency. It places the university in charge of a multi-center, five-year effort aimed at definitively determining the value of the new class of atypical anti-psychotic drugs represented by clozapine, risperidone, olanzapine and quetiapine.

“This research will make an unparalleled contribution to defining the clinical role of the new anti-psychotics,” said Dr. Steven E. Hyman, director of the NIMH. “It will provide reliable data on the efficacy of these atypical medications in relieving psychotic symptoms of schizophrenia and Alzheimer's disease, and will gauge their effectiveness in terms of broader outcomes — such as adherence to treatment, ability to work, social functioning and quality of life.”

Now on the market, these drugs are proven effective in carefully controlled clinical studies typically co-sponsored by drug companies. The drugs differ from other anti-psychotic agents in that they act on multiple cell receptor sites in the brain, including receptors for dopamine, serotonin and norepinephrine, instead of just dopamine.

However, the new drugs cost more than 10 times that of the old medications and questions remain about their effectiveness in the real world and whether they are worth the higher price.

“The NIMH wants to get definitive and objective results in terms of their effectiveness, results of significant magnitude in real world settings that can inform public health policy,” said Dr. Jeffrey A. Lieberman, professor of psychiatry, pharmacology and radiology at UNC-CH School of Medicine.

Lieberman and Dr. C. E. Davis, professor and chair of biostatistics at the UNC-CH School of Public Health, are the project's co-principal investigators. Over the next five years, they and their study

colleagues will enroll 1,000 patients with schizophrenia and 400 to 500 Alzheimer's patients. The terms of the NIMH award include an option for expansion studies and a five-year extension.

Federal grants are outright forms of financial assistance for university-derived research ideas. Contracts, on the other hand, stem from federal research needs and are awarded after universities competitively bid for them through requests for proposal, called RFPs.

Lieberman said several key factors contributed to UNC-CH's successful bid.

"The university and the psychiatry department have a long tradition of research in the pathological basis of mental illness and the development of therapeutic strategies," he said.

UNC-CH also has experience conducting large, multi-center trials, including serving as the lead institution for ongoing multi-center studies on atypical anti-psychotic drugs in North America and Europe.

"There is a pre-existing research history here with an infrastructure," he said. "The School of Public Health has a lot of experience acting as a coordinating center for large-scale, multi-center trials. That expertise helped make us very competitive for the award."

In a multi-center effort, UNC-CH will subcontract to other academic institutions to assist in coordinating the trials, involving faculty from Duke University, the University of Southern California, Yale University and the University of Rochester. They will enlist 50 clinical sites for the enrollment of patients and performance of the study. Quintiles Transnational Inc., based in the Research Triangle Park, will help manage the study sites.