Brief Description of the Biomarker and Safety Study of Clozapine for Patients with BEN

Clozapine is the most effective antipsychotic for the treatment of schizophrenia, however it is underused particularly in the African American (AA) population. Low Absolute Neutrophil Counts (ANC), either baseline or during treatment is a significant barrier to clozapine use in AA patients. Our pilot work finds that discontinuation of clozapine (particularly for neutropenia) in AA patients is over twice that in Caucasians. Recently the phenomenon of Benign Ethnic Neutropenia (BEN) in AAs has gained attention and it may be linked to a genetic polymorphism.

Despite the new FDA guideline changes around new guidelines in BEN patients there have been no prospective studies to examine clozapine safety in BEN patients and this is the first study to do so. Our study will aim to initiate clozapine in 250 patients (primarily but not solely AA) and examine the safety of use and the risk of severe neutropenia. Our study will evaluate ANC before and during 6 months after clozapine initiation and look at the safety of clozapine and patterns of ANC fluctuation.

We will work closely with physicians to help them initiate and monitor clozapine and provide expert collaboration and consultation. Study visits will generally consist of a blood draw, vital signs, and side effects check. Participants are compensated for their time. The study is being conducted by Dr. Deanna Kelly [http://www.medschool.umaryland.edu/profiles/Kelly-Deanna/] and her team at the Maryland Psychiatric Research Center, Treatment Research Program in Catonsville, MD, part of the University of Maryland School of Medicine.

For more information contact Matt Glassman: 410-402-6411 or mglassman@som.umaryland.edu.