

## Schizophrenia Trials at UC Davis

### Contact Information

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### Partnering goals

Phase I, II, III clinical trials for the following indications: schizophrenia, cognitive and negative symptoms,

### UC Davis Translational and Clinical Neuroscience

#### Research Support:

- 6- Faculty
- 2 - Clinical Research Coordinators
- 1- MRI technologist, 2 medical physicists, 1 EEG technician
- 7-research technicians

### Sacramento Area – Enrollment opportunities

The Greater Sacramento area houses over 1.8 million people. The area enjoys high ethnic diversity, and a variety of airway disease phenotypes. As of January 2008, the ethnic distribution in the area was as follows: 48% Whites (including the second largest Eastern European population in the US), 21.6% Hispanics, 15.5% Black, 16.6% Asian (among them more than 50% Laotian/Hmong, and Vietnamese), 0.9% Pacific Islanders, 1.3% American Indians. Foreign born population 20.3%, and 41.5% of them are naturalized citizens.

### Recent Asthma and COPD Clinical Trials Performed at UC Davis, Pulmonary/Critical Care Division

Clinical Trial	Indication	Trial Type	Enrollment	Status
Modafinil effects on cognition and brain activity (fMRI/induced gamma band activity) in schizophrenia (PI: M. Minzenberg)	Impaired cognition in schizophrenia	Clinical trial	Ongoing n=32	Currently enrolling
Pathophysiology of cognitive disability in	Severe	Clinical	Ongoing (55	Currently

schizophrenia NIMH PI Carter (fMRI, EEG, genetics)	first episode schizophrenia, affective psychoses	research	subjects to date)	enrolling
<b>Cognitive and emotional processing in schizophrenia</b> (PI: Carter, Co-PI: S. Ursu)	schizophrenia	Clinical research	Ongoing 45 enrolled	Currently enrolling
<b>Cognitive neuro rehabilitation in early schizophrenia</b> <b>Stanley foundation local PI Carter</b>	Early schizophrenia	Clinical trial	Ongoing (6 subjects consented to date)	Currently enrolling
<b>Cognitive neuro rehabilitation in prodromal schizophrenia</b>	Prodromal schizophrenia	Clinical trial	starts/July 08	Currently enrolling
<b>EDIPPP (Early intervention to prevent psychosis)</b> <b>Robert Wood Johnson Foundation</b>	Schizophrenia high risk	Effectiveness study	12 subjects randomized	ongoing.

### *Additional Facilities for Phase 0 and Phase I Studies*

#### **Imaging Research Center/Imaging Biomarkers**

*Dr Carter and his research group are world leaders in the use of functional MRI to investigate schizophrenia and to non-invasively measure the effects of treatment on the brain in this illness and have over 15 years experience with functional neuroimaging.* Their clinical neuroscience laboratory is located within the UC Davis Imaging Research Center on the campus of the University of California at Davis Medical Center in Sacramento. The lab is directed by Cameron Carter MD, Professor of Psychiatry and Psychology, who also directs the Imaging Research Center. The Imaging Center has two research dedicated scanners, a 1.5 T GE Signa scanner and a 3T Siemens TRIO, with 8 channel phased array head coil for high resolution neuroimaging. A Neuroscan 128 channel EEG systems is installed in a sound, light and RF shielded booth, and the lab is well supported with computational resources and software tools for ERP/EEG and fMRI data analysis and display. A CTSC Nurses Station is located near the 3T scanner where the CTSc nursing staff conduct patient assessments, blood draws, EKG's etc.

Within the IRC, there is dedicated space for participant behavioral testing as well as for clinical interviews of patient participants. There is also adequate office space for postdoctoral fellows and research assistants. Within the lab, there are numerous projects examining cognition, affect and motivation in various schizophrenia patient populations, including prodromal, first-break, early psychosis and chronic populations. In addition to the multiple lab projects examining wide-ranging issues in cognitive control, current research in the lab incorporates basic affective neuroscience as well as clinical and basic research in cognition/emotion interactions.

Patient participants for research are recruited from the EDAPT (Early Diagnosis and Preventive Treatment) Clinic in the Department of Psychiatry, where approximately 100

patients with onset of schizophrenia or related psychotic disorders are seen, from community clinics in the Sacramento region that are staffed by Department of Psychiatry Faculty and Residents, as well as private hospitals and clinics where individuals with psychotic disorders are treated. Patient characterization is undertaken using standardized structured clinical interviews (SCID, K-SADS, SIPS) and clinical ratings by Doctoral and Masters level clinicians and reliability is established and maintained in bi-weekly reliability rounds overseen by Dr Ragland.

**The CTSC Clinical Research Center** is a dedicated clinical research facility accessible by any UCDMC staff physician for Phase 0 and Phase I clinical trials. These facilities are governed by the National Center for Research Resources (NCR), a center of the National Institutes of Health (NIH) under the Clinical and Translational Science Award program.

The UC Davis CCRC is a collaboration between the University and the Veterans Affairs Northern California Healthcare System (VANHC). The CCRC is located in an 8,000-square-foot area on the fourth floor in the new inpatient tower at the Sacramento VA Medical Center at Mather, about 10 miles east of the UC Davis Medical Center in Sacramento.

The nine-bed facility consists of three double and three single-patient rooms, a designated metabolic kitchen, a core laboratory, a body composition unit, videotaping facilities and offices for biostatistics, informatics and the administrative staff. In addition, the center has all the resources required for an inpatient facility, including a communication center, utility rooms, diagnostic area, storage facility and patient day room. Adjacent to the CCRC is a state-of-the-art imaging facility including PET, MRI and standard radiology equipment available to CCRC users.

The CCRC is staffed with thirteen highly skilled RNs provide 24/7 care to subjects enrolled in clinical research studies at CCRC and on the main campus. RNs are specially trained in Human Subjects Protection, Good Clinical Practices, and Research Protocol Adherence; all are Chemotherapy, Conscious Sedation, and ACLS certified. Exercise Physiologist has a variety of methods of measuring body composition, bone density, metabolic rate and exercise fit. The CCRC houses a BOD POD, DEXA machine, Metabolic Cart, 12 Lead EKG Stree Treadmill system and much more. Research Dietitian provides nutritional support to study protocols by providing nutritional analysis, designing specialized meal plans, providing nutritional counseling to subjects, and on-site food preparation

### *CTSC Clinical Research Center Laboratory*

The Laboratory Core manages the collection, flow and disposition of biological specimens collected for CCRC studies.

#### *Specimen Processing*

-SOP's for specimen processing are written to ensure that all specimens (single or multiple blood, serum, plasma or urine) are collected and processed in accordance with the approved instructions specific for each protocol

#### *Clinical Analysis*

UCDHS Clinical Pathology Services is a primary laboratory for routine analysis for the CCRC. The VAMC Clinical Lab will assist the GCRC in situations that require STAT lab results.

#### *Specimen Storage*

The Core Laboratory has a 4°C refrigerator, one upright -20°C and three -80°C freezers for short term specimen storage, monitored daily for temperature control.

#### *Specialized Analyses:*

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The laboratory personnel can help with isolation of cells from peripheral blood, flow cytometry as well as isolation of DNA/RNA and other esoteric testing as necessary for the different protocols.

*Multiplexing on the Bioplex and BD FACS Array:*

2 different platforms are available for multiplexing and in combination provide a variety of tests that can be multiplexed according to the needs of a particular protocol