

Clinical Core

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Overarching Aim of the Clinical Core

- Increase knowledge about the role of metabolic and vascular risk factors in promoting the transition from normal aging to MCI, and then to AD or other forms of pathological brain aging such as vascular cognitive impairment (VCI).
- Our Charge:
 - Establish a well characterized cohort of participants
 - Be a resource to you!
 - We want to share our data
 - Participants are able to be in other studies

Clinical Core Specific Aims

- 1:** To enroll and intensively characterize a cohort of participants with and without prediabetes who are cognitively normal, have MCI, or have Alzheimer's or mixed dementia
- 2:** To provide resources to address the question of whether participants with prediabetes show greater change over time on measures of cognition and AD pathology, and to explore relationships among novel AD and metabolic biomarkers and symptoms of AD, VCI, and other disorders.
- 3:** To maximize the participation of African American adults and others from diverse racial and ethnic backgrounds, who have higher rates of metabolic and vascular disease, and dementia.
- 4:** To coordinate systematic collection and archiving of brain, biospecimen, genetic, cognitive, metabolic, and imaging data to share with national and local investigators
- 5:** To develop and collect innovative indices of metabolic and vascular risk

Clinical Core Composition

500 participants, ≥ 55 years old

Normal

Normoglycemic
N=75; low risk

Pre-Diabetic
N=125; high risk

MCI

Normoglycemic
N= ~125

Pre-Diabetic
N= ~125

AD/ mixed VCI

N= 50

Diabetes excluded

Assessments

- **Uniform Data Set-3**
 - Interview and Physical exam
 - Cognitive assessments: 1.5 hour battery of tests
 - Medications and comorbid conditions
 - Family history
 - Informant reported measures of function, behaviors
- **Labs** (CMP, CBC, TSH, B12, HA1c, insulin, lipids; Apo-E genotype; CSF a- β , t-tau, p-tau)
- **OGTT, DXA, Arterial stiffness**
- **Neuroimaging**
 - MRI on all
 - Amyloid PET & dual AcAc/FDG PET in subset; possibly Tau PET
- **Blood, DNA, and CSF stored**

Assessment Schedule

	Y1			Y2			Y3			Y4			Y5		
	NL	MCI	AD	NL	MCI	AD	NL	MCI	AD	NL	MCI	AD	NL	MCI	AD
Key assessments															
UDS	X	X	X		X	X		X	X	X	X	X		X	X
Blood	X	X	X							X	X	X			
MRI	X	X	X							X	X				
DXA	X	X	X							X	X	X			
OGTT	X	X	X							X	X				
PWV	X	X	X												
Bio-intensive Group															
CSF	S	S	S							S	S				
PiB PET	S	S	S							S	S				
Dual tracer PET ¹	S	S	S							S	S				
Phone assessment ²				X			X						X		

NL=cognitively normal (metabolically normal and pre-diabetic); X= collected at the visit; S= Bio-intensive group (BIG) substudy participants only; Goal enrollment is 50% CSF, 20% PiB; 15% dual tracer; 1. Dual tracer PET= FDG + Acetoacetate PET; 2. Telephone Assessment: screen positive participants will be brought in for a complete UDS clinical and cognitive assessment and if determined to have clinically significant decline will follow annual assessments on same schedule as MCI participants.



We hope you'll find ways to use the resources we are building