Alzheimer's and Cognition Center
UNIVERSITY OF COLORADO **ANSCHUTZ MEDICAL CAMPUS**

HEALTHY BRAIN AGING

- Starts Here -

2021 Research Study Catalog

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Information contained in this pamphlet is accurate as of print date. Please confirm with the study coordinator for updates on studies that may not be reflected in this catalog, or visit the CU Alzheimer's and Cognition Center website at:

www.cumemoryresearch.org

The information contained in this catalog is not to be used as medical advice. If you or someone you know is concerned about their memory or brain health, please consult your health care provider.

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Frequently Asked Questions

I am interested in participating in research, but don't know where to start. What should I do?

A great place to start would be to contact our recruitment specialists at NeurologyResearchPartners@cuanschutz.edu or 303-724-4644. They can tell you more about research in general and answer any other questions you may have.

I think I might be eligible for one of these studies. What is the next step in the process?

Call or email the coordinator listed for the study you think you are interested in. The coordinator will go through a brief pre-screening questionnaire with you over the phone—takes about five minutes—to see if you are a good fit. If you meet the initial screening requirements, the coordinator will work with you to schedule a more detailed, in-person screening visit. You can also reach out to our recruitment specialists at NeurologyResearchPartners@cuanschutz.edu or call them at 303-724-4644 if you are interested in more than one study.

What do I do if I want to participate in research, but none of these studies are for me?

The Neurology Department has many ongoing studies not listed in this catalog that investigate other neurological disorders and diseases. We would be happy to talk with you more and learn what type of research you are interested in, and see if we can find a study for you. Even if we can't find a study right now, new studies are always starting in our department, and we can keep your information in our database to contact you in the future. Contact us at:
NeurologyResearchPartners@cuanschutz.edu or 303-724-4644 or go to www.cumemoryresearch.org

I really want to get involved in research, but I just don't have the time right now. What can I do?

Feel free to give us a call anyway! We can take down your information and keep you in our database, so when you have more time, we can give you a call.

Is participating in research voluntary?

Yes! All research is voluntary. You can stop participation and withdraw from a study at any time, and there will be no hard feelings.

Observational Studies

The following section of studies are called observational studies. Observational studies do not involve an intervention (i.e., a possible new drug or treatment). Instead, people volunteer their time to let researchers observe and study certain behavior patterns and collect biological samples such as blood samples, brain images through MRI or PET scans, and cerebrospinal fluid (CSF) samples. Observational studies can be, but are not always, longitudinal, meaning the same person returns at a certain point in the future to do the same tasks again, so that responses can be compared over time.

The observational studies we do here at the CU Alzheimer's and Cognition Center aim to carefully characterize a group of aging adults so that we can better understand what may put certain individuals at risk for later cognitive decline and how to prevent it. Our current observational studies follow aging adults – both symptomatic participants, meaning adults who have been diagnosed with mild cognitive impairment (MCI), Alzheimer's disease, or another form of dementia, adults with down syndrome, and asymptomatic participants, meaning healthy aging adults with no current symptoms.

Longitudinal Biomarker and Clinical Phenotyping (Bio-AD)

Title: Longitudinal Biomarker and Clinical Phenotyping Research Study

Principal Investigator: Dr. Brianne M. Bettcher, PhD

Protocol: COMIRB #15-1774

For more information about the research study, please contact:

Study Coordinator: Trevor Sooy, BA

Email: Trevor.Sooy@cuanschutz.edu

Phone: 303-724-8971

Website: ColoradoAgingBrain.org

Major Goals of this Research Study

- Help understand why Alzheimer's disease and its symptoms differ between aging adults.
- Identify different "biological footprints" that can help predict individuals most likely to develop Alzheimer's disease, and those most likely to be protected.
- Collect important data on brain aging to be used by researchers to: determine who is at most risk for Alzheimer's disease and why, to improve early diagnosis of neurodegenerative diseases in aging adults, and to inform the development of novel treatments and therapies.

Why Is this Research Important?

This research study is a longitudinal study, meaning participants return multiple times over the course of four years. Longitudinal studies of aging and Alzheimer's disease are important as we expand our understanding of the aging process and of factors that put individuals at greater risk for cognitive decline. Participants in this research study will provide us with critical information about aging trajectories, so that we as researchers can learn more about what puts an individual at risk for Alzheimer's disease and related dementias, what factors protect an individual against developing symptoms, and what screening methods are needed to identify risk factors early enough so that we can enroll someone in a clinical trial before they begin to show symptoms.

Inclusion/Exclusion Criteria

You may be eligible for this research study if you:

- Have a study partner available to complete a questionnaire about your functional abilities each year

We are currently recruiting the following groups*

Healthy older adults from diverse backgrounds, 60 years and older	Adults w/ a confirmed diagnosis from a doctor of Alzheimer's disease (AD) 65 years or older, or Mild Cognitive Impairment due to AD, 55 years or older	Individuals w/ a clinical diagnosis of Down Syndrome, 30 years and older	Adults diagnosed w/ an atypical form of Alzheimer's disease (i.e., Posterior Cortical Atrophy)

*Depending upon study recruitment needs, active enrollment of some groups may change. Please contact the study coordinator for information.

Please note: This is a brief summary of basic screening criteria. A complete list can be found at http://bit.ly/Bio-AD. Additional things may come up during the course of screening that impact enrollment eligibility, which is ultimately up to the discretion of the study team.

What Will Happen at the Visits

	Screening and Baseline Visit*	Year 2	Year 3	Year 4
Eligibility Review	X			
Informed Consent	X			
Medical Record Review	X	X	X	X
Neurological/Physical Exam	X	X	X	X
Questionnaires, Health Survey	X	X	X	X
Blood Draw	X	X	X	X
Cognitive and Mood Assessments	X	X	X	X
Brain MRI**	X	X		
Study Partner Questionnaire	X	X	X	X
Lumbar Puncture (optional)	X	X	X	X

*Screening procedures (highlighted gold) may be completed on the same day as aspects of the baseline visit. If you do not meet the screening criteria, you would not complete the remaining baseline visit procedures.

**Optional for participants with Down Syndrome.

Time Spent: All study visit procedures take about 4-5 hours to complete, with an additional hour for visits with an MRI. The study partner questionnaire takes about 30 minutes and may be able to be done over the phone. The study visit will be repeated every year, requiring about the same amount of time.

Compensation: This study does not provide compensation. Participant will receive:

- Snacks and Refreshments

Immunity, mTBI, and Alzheimer's Biomarkers (ImTAB)

Title: An Investigation of Immune Biology and Alzheimer's Disease related Biomarkers in Asymptomatic, Late Life mild TBI

Principal Investigator: Dr. Brianne M. Bettcher, PhD

Protocol: COMIRB #19-1423

For more information about the research study, please contact:

Study Coordinator: Erika Dallmann, BS

Email: Erika.Dallmann@cuanschutz.edu

Phone: 303-724-2540

Website: ColoradoAgingBrain.org

Sponsor: Department of Defense

Major Goals of this Research Study

- Investigate how structural changes in the brain relate to memory and cognitive changes.
- Collect and analyze fluid biomarkers for the detection of inflammation and Alzheimer's disease related risk factors.
- Examine the relationship between concussion and the aging process.

Why Is this Research Important?

This research study is examining how a concussion sustained in late life relates to inflammation and brain health. The immune system is vital for protecting us against pathogens (i.e., diseases and viruses), but goes through important changes as we age. Some of these changes have been linked to the development and progression of Alzheimer's disease, but more information is needed to understand the relationship between the immune system and memory, and what factors drive these changes. This research study will help us as researchers to better understand how concussion may or may not disrupt thinking, the immune system, and brain health in late life.

Inclusion/Exclusion Criteria

You may be eligible for this research study if you:

- Are 65 years or older
- Sustained a concussion within the past 5 years but not within the past 6 months
- Talked with your doctor about your concussion
- Have not been diagnosed with a memory disorder
- Have no factors that make you unable to have an MRI (i.e. pacemaker)
- Are willing to return for a 1-year follow-up research appointment

Please note: This is a brief summary of basic screening criteria. A complete list can be found at http://bit.ly/ImTAB-study. Additional things may come up during the course of screening that impact enrollment eligibility, which is ultimately up to the discretion of the study team.

What Will Happen at the Visits

	Screening and Baseline Visit*	Email Follow-ups	12 Month Follow-Up Visit
Eligibility Review	X		
Informed Consent	X		
Brief Cognitive Screening Exam	X		
Study Partner Questionnaire	X		X
Neurological/Physical Exam	X		X
Interview, Questionnaires	X		X
Computer Health Survey	X	X	X
Blood Draw	X		X
Cognitive and Mood Assessments	X		X
Brain MRI	X		X

*Screening procedures (highlighted gold) may be completed on the same day as aspects of the baseline visit. If you do not meet the screening criteria, you would not complete the remaining baseline visit procedures.

Time Spent: All study visit procedures take about 6 hours to complete and can be split up over multiple days. The study partner questionnaire takes about 30 minutes and can be done over the phone. The visit will be repeated one year later, requiring about the same amount of time.

Compensation: Participant is given $25 after completion of the 12 month follow-up visit. They will also receive:

- Snacks and Refreshments
- Optional review of cognitive assessment scores with investigator after completion of 12 month follow-up visit

Longitudinal Innate Immunity and Aging (LIIA)

Title: Investigating the Contribution of Peripheral Versus Central Nervous System Immune Dysfunction to Cognitive Aging

Principal Investigator: Dr. Brianne M. Bettcher, PhD

Protocol: COMIRB #18-2607

For more information about the research study, please contact:

Study Coordinator: Katrina Bengtson, BA

Email: Katrina.Bengtson@cuanschutz.edu

Phone: 303-724-2048

Website: ColoradoAgingBrain.org

Major Goals of this Research Study

- To better understand how inflammation may or may not disrupt thinking and memory.
- To learn more about how immune system markers, measured in the blood and in the spinal fluid, are related to clinical features of aging over time.
- To better understand how different types of biomarkers may relate to immune health and the aging process.
- To investigate how exposure to COVID-19 relates to brain and memory outcomes.

Why Is this Research Important?

The immune system is vital for protecting us against pathogens (i.e., diseases and viruses). However, as we age, there are important changes in the immune system, and it can become dysregulated. Some of these changes have been linked to the development and progression of Alzheimer's disease; however, we do not fully understand at this point whether inflammation – and immune change more broadly – is a driver of cognitive decline. This research study is important because it will help us to better understand how the body's immune system interacts with the brain's immune system and determine whether this affects the aging process. This will allow researchers to better understand what puts us at risk for Alzheimer's disease, as well as what protects us from Alzheimer's disease.

Inclusion/Exclusion Criteria

You may be eligible for this research study if you:

- Are 60 years or older
- Have a reliable study partner who has frequent (i.e., at least twice per month) contact with you
- Have NOT been diagnosed with a memory disorder
- Have no factors that preclude lumbar punctures (e.g., lower back surgery)
- Have no factors that preclude having an MRI (e.g., pacemaker)
- Are willing to complete both baseline and 24-month follow-up procedures

Please note: This is a brief summary of basic screening criteria. A complete list can be found at http://bit.ly/LIIAstudy. Additional things may come up during the course of screening that impact enrollment eligibility, which is ultimately up to the discretion of the study team.

What Will Happen at the Visits

	Screening and Baseline Visit*	Email Follow-Ups (3 total)	24 Month Follow-Up Visit
Eligibility Review	X		
Informed Consent	X		
Medical Record Review	X		X
Brief Cognitive Screening Exam	X		
Study Partner Questionnaire	X		X
Neurological/Physical Exam	X		X
Interview, Questionnaires	X		X
Health Survey	X	X	X
Blood Draw	X		X
Lumbar Puncture	X		X
Cognitive and Mood Assessments	X		X
Brain MRI	X		
SARS-CoV-2 antibody test (results provided)	X		X

*Screening procedures (highlighted gold) may be completed on the same day as aspects of the baseline visit. If you do not meet the screening criteria, you would not complete the remaining baseline visit procedures.

Time Spent: All study visit procedures take about 8 hours to complete and will be split up over multiple days (e.g. three study visits). The study partner questionnaire takes less than 30 minutes and can be done over the phone. The visit will be repeated two years later, requiring about the same amount of time. Email follow-ups are sent every six months and take about ten minutes to complete.

Compensation: Participant is given $75 for the completion of each lumbar puncture, and an additional $50 if all study visits (baseline and follow-ups) are completed. They will also receive snacks, refreshments, their SARS-CoV-2 antibody test results, and their Vitamin B-12 level results.

Palliative Care Preferences of Patients and Care Partners in Early Onset Dementia

Title: Perceived Palliative Care Needs in Early-Onset Dementia (EOD)

Principal Investigator: Dr. Christina L. Vaughan, MD, MHS

Protocol: COMIRB #19-2134

For more information about the research study, please contact:

Study Coordinator: Natalie Lopez-Esquibel, BS

Email: Natalie.Lopez-Esquibel@cuanschutz.edu

Phone: 303-724-7937

Website: www.cumemoryresearch.org

Major Goals of this Research Study

- Identify the perceived palliative care needs and care preferences of patients who are affected by early-onset dementia (EOD) and their care partners.
- Understand the potential experiential differences that exist between EOD and typical, late onset Alzheimer's disease and related dementias.
- Contribute to growing literature on neuropalliative care for people living with dementia.

Why Is this Research Important?

Early-onset dementias, compared to the more typical late onset dementias, are usually more severe with greater rates of decline and bigger impacts on life expectancy. These patients require different levels of support due to their younger age of onset (less than 65 years of age), with higher rates of behavioral disturbances and greater need for caregiver support. More information is needed regarding their experiences and, in particular, unique challenges of both patients and caregivers compared to those with late onset. By revealing the unique challenges and unmet needs in EOD we will empower future research which aims to improve dementia care for this patient population.

Inclusion/Exclusion Criteria

You and your care partner may be eligible to participate in this study as a pair if:

- You are both 18 years or older
- One member of the pair has been diagnosed with Alzheimer's disease or Frontotemporal dementia and had symptoms that began before the age of 65*
- The other member of the pair is a care partner

*Depending upon study recruitment needs, active enrollment of some diagnoses may change. Please contact the study coordinator for information.

Please note: additional things may come up during the course of screening that impact enrollment eligibility. which is ultimately up to the discretion of the study team.

What Will Happen at the Visit

	Study Visit*
Eligibility Review	X
Informed Consent	X
Health Questionnaires	X
Interview	X
Care Partner Questionnaires (conducted separately)	X

*If you do not meet the screening criteria (determined during procedures highlighted in gold), you would not complete the rest of the visit.

Time Spent: This research study inolves a single, one-hour in-person or telephone interview with a pair of participants and separate phone questionnaires for care partners.

Compensation: This research study does not provide compensation.

Conversational Speech Analysis (CSA) Research Study

Title: Conversational Speech in the Diagnosis of Neurocognitive Disorders

Principal Investigator: Dr. Peter Pressman, MD

Protocol: COMIRB #18-0456

For more information about the research study, please contact:

Study Coordinator: Francesca Dino

Email: Francesca.Dino@cuanschutz.edu

Phone: 303-724-6103

Website: www.cumemoryresearch.org

Major Goals of this Reseach Study

- Learn more about how speech changes over time in adult populations.
- Understand more about how changes in speech reflect changes in cognition.
- Develop diagnostic tools that can be used by primary care providers for early recognition of Alzheimer's disease and related disorders.

Why Is this Research Important?

Conversational speech, or the speech that happens spontaneously between two people, such as a patient and their doctor, may show changes as a result of neurological disease. These changes may occur not just in what the person says, but how they say it. This research study is important because it hopes to help build diagnostic tools that can identify these changes in conversational speech to facilitate earlier and more accurate recognition of Alzheimer's disease and related disorders. This is important, because using elements of conversational speech such as tone of voice and duration of speaking could be a cheap, non-invasive way to gather information that can be used to detect cognitive changes earlier, as well as direct medical interventions that will help slow or prevent the progression of neurological disease.

Inclusion/Exclusion Criteria

You may be eligible for this study if you:

- Are between the ages of 40-95
- Have a reliable study partner who you have known for at least 1 year
- Are primarily English speaking, without distinctive regional or international dialect

Please note: This is a brief summary of basic screening criteria. A complete list can be found at http://bit.ly/speech-study. Additional things may come up during the course of screening that impact enrollment eligibility, which is ultimately up to the discretion of the study team.

What Will Happen at the Visit

	Screening and Baseline Visit*	12-month Follow-up Visit
Eligibility Review	X	
Informed Consent	X	
Hearing Test	X	X
Recording of Conversation	X	X
Physiological recordings (heart rate, etc.)	X	X
Language and Emotion tasks	X	X
Cognitive Testing**	X	X

*If you do not meet the screening criteria (determined during procedures highlighted in gold), you would not complete the rest of the visit.

**Cognitive testing procedures may vary based on prior participation in CUACC research studies (e.g. Bio-AD, LIIA).

Time Spent: The study visit lasts approximately 6-8 hours. The visit will be repeated two years later, requiring about the same amount of time. Time spent may be shortened based on prior participation in CUACC research studies.

Compensation: A $40 gift card will be given to participants.

Clinical Trials

The studies in this section are clinical trials. Clinical trials study an intervention, such as a drug or a device, that could produce a potential change in the way a disease or medical condition is detected, prevented, managed, or treated. The intervention can be brand new, or it could be something that has been used before to treat other diseases but may now be able to used for a different disease. The purpose of clinical trials are to study the 1. safety of the intervention, and 2. the efficacy, or effectiveness, of the intervention. Clinical trials go through multiple phases before the intervention is determined to be able to be made available to the public.

PLEASE READ: The interventions listed in this section do not indicate evaluation or approval by the Food and Drug Administration (FDA). There are risks and potential benefits associated with every clinical trial, and we recommend speaking at length with the study coordinator, your health care provider, and any other interested parties within your family or social circle before participating in a trial.

INFRONT-3

Title: A Phase 3 Study to Evaluate Efficacy and Safety of AL001 in Frontotemporal Dementia

Sponsor: Alector Inc.

Principal Investigator: Peter Ljubenkov, MD University of California, San Francisco

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Contact: Study Lead

Phone: 1-833-346-3383

Email: clinicaltrials@alector.com

ClinicalTrials.gov Identifier: NCT04374136

Brief Summary: A phase 3 double blind, placebo controlled study evaluating the efficacy and safety of AL001 in participants at risk for or with frontotemporal dementia due to heterozygous mutations in the progranulin gene.

Ages Eligible for Study: 25 Years to 85 Years

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