University of Colorado **Anschutz Medical Campus**

Department of Neurology

Research Catalog | Volume 1, Issue 1

Over the years, we have talked to so many individuals who are interested in neurology clinical research opportunities at the University of Colorado Anschutz Medical Campus and who want to be updated on future opportunities—individuals just like you! It was your commitment to research that inspired this semiannual Neurology Research Catalog—a way to provide updates on our research opportunities to those whom we have seen in clinic and/or have consented into our Neurology Recruitment Database. This catalog contains a list of our currently enrolling research studies, organized by diagnosis, and the key eligibility criteria required for participation in each study. We sincerely value your time and consideration of our research and hope you find this catalog informative.

One of our goals is to offer ways for monolingual Spanish speaking people to participate in our research program. If you are not comfortable participating in English and are fluent in Spanish, please reach out to Neurology Research Partners at NeuroResearch@cuanschutz.edu or 303-724-4644 to learn more about our neurology research opportunities available in Spanish. We hope to continue extending our research program to more communities with additional languages.

Thank you for your passion for research and desire to help others—your consideration and generous participation is imperative to our research. Please reach out to Neurology Research Partners at NeuroResearch@cuanschutz.edu or 303-724-4644 if you are interested in research studies enclosed in this catalog and keep an eye out for future catalog issues.

University of Colorado **Anschutz Medical Campus**

Department of Neurology

Research Catalog | Volume 1, Issue 1

En los últimos años, hemos hablado con muchas personas que están interesadas en las investigaciones del Departamento de Neurología en la Universidad De Colorado Anschutz Medical Campus y que desean en un futuro la oportunidad de participar en estos estudios clínicos – ¡personas como usted! Ha sido el compromiso de nuestros participantes que inspiro este catálogo semestral – una forma de proporcionar actualizaciones sobre nuestras oportunidades de investigación a aquellos a quienes hemos visto en la clínica y/o han dado su consentimiento para nuestra base de reclutamiento de datos en neurología. Este catálogo contiene una lista sobre nuestras investigaciones que están reclutando participantes, organizada por diagnóstico, y los criterios de inclusión requeridos para participar en cada estudio. Nosotros valoramos su tiempo y su consideración para nuestros estudios de investigación. Esperamos que este catálogo sea útil para usted.

Una de nuestras metas es ofrecer oportunidad de participación a las personas que hablan español. Si usted no se siente cómodo hablando en inglés y prefiere hablar en español, por favor comuníquese con nosotros al (303)-724-4644 Neurology Research Partners; o envié un correo electrónico a NeuroResearch@cuanschutz.edu para conocer sobre nuestras oportunidades de investigación disponibles en español. Esperamos continuar nuestro programa de investigación y expandirnos a comunidades de habla hispana.

Gracias por su pasión a la investigación y deseo de ayudar a otros – su consideración y generosa participación es importante e indispensable para el éxito de las investigaciones. Comuníquese con Neurology Research Partners en NeuroResearch@cuanschutz.edu o 303-724-4644 si está interesado en los estudios de investigación incluidos en este catálogo y esté atento a futuras ediciones

Volume 1.1.0

February 9, 2022

Information contained in this catalog is accurate as of print date. Please confirm with the study staff for updates on studies that may not be reflected in this catalog, or visit the University of Colorado, Department of Neurology website: https://medschool.cuanschutz.edu/neurology/research/clinical-research

Please note that this catalog only includes basic eligibility requirements. The study staff will discuss the full eligibility criteria and only people who meet all criteria will be enrolled.

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

If you are interested in scheduling an appointment with a neurology provider, please contact our clinic at (720) 848-2080.

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Helpful Definitions

Clinical study: a research study involving human participants that is intended to add to medical knowledge. There are two types of studies: interventional and observational.

- Interventional study: a type of clinical study in which participants are assigned to groups that receive one or more interventions/treatments so that researchers can evaluate the effects of the interventions on biomedical or health-related outcomes.
- Observational study: a type of clinical study where participants are observed for biomedical or health outcomes. Participants may receive interventions, but the investigator does not assign participants to specific interventions.

Clinicaltrials.gov: a Web-based resource that provides patients, their family members, health care professionals, researchers, and the public with easy access to information on publicly and privately supported clinical studies on a wide range of diseases and conditions.

Eligibility criteria: the key requirements that people who want to participate in a clinical study must meet or the characteristics they must have.

Informed consent: a process used by researchers to communicate to potential and enrolled participants what the trial involves. Participants must understand what will be done in the trial, how the protocol works, what risks/discomforts they may experience, and that participation in the trial is a voluntary decision.

Principal investigator: the person who is responsible for the scientific and technical direction of the study (e.g., a neurologist or PhD-level researcher).

Placebo: an inactive substance or treatment that looks the same as and is given in the same way as the active intervention/treatment being studied.

Masked: clinical trial design strategy in which one or more parties involved in the trial, such as the investigator or participants, do not know which participants have been assigned to which intervention. Types of masking include: open-label, single -blind masking, and double-blind masking.

Helpful Definitions (cont.)

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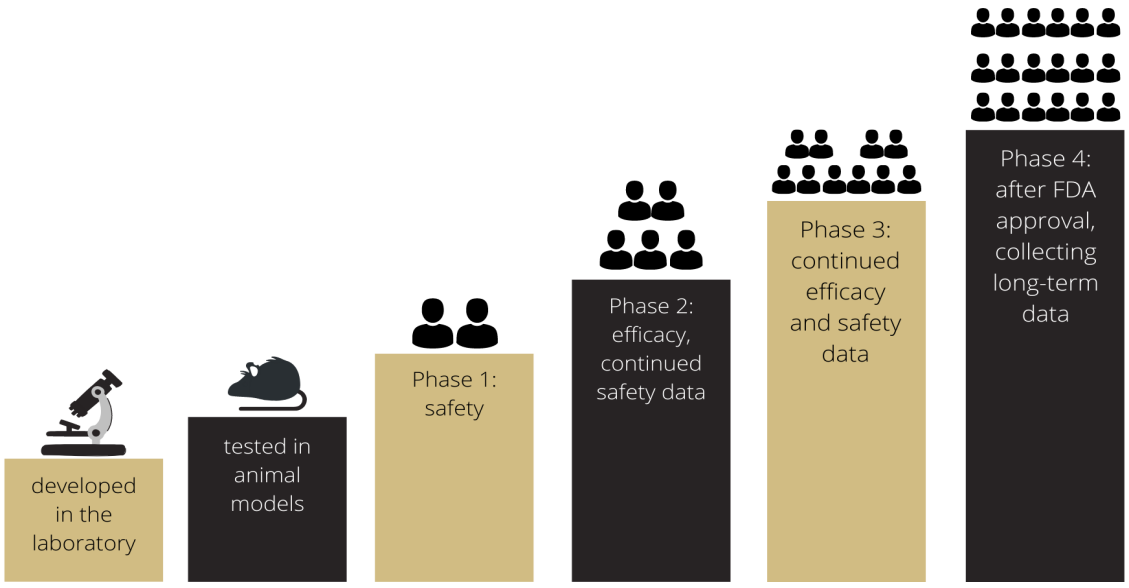
Open-label extension: a trial that follows an original randomized clinical trial. In an open-label extension study, all participants receive the study drug (rather than placebo) and additional safety data is collected. Typically only open to people who participated in the randomized trial.

Randomized: a type of trial where participants are allocated to a study group (e.g. placebo or active treatment) by chance.

Phase: the stage of a clinical trial studying a drug or biological product, based on definitions developed by the U.S. Food and Drug Administration (FDA). The phase is based on the study's objective, the number of participants, and other characteristics.

- Phase 1: clinical trials that focus on the safety of a drug. They are usually conducted with healthy volunteers and involve a small number of participants.
- Phase 2: clinical trials that gather preliminary data on whether a drug works in people who have a certain condition/disease (that is, the drug's effectiveness).
- Phase 3: clinical trials that gather more information about a drug's safety and effectiveness by studying different populations, different dosages, and by using the drug in combination with other drugs.
- Phase 4: clinical trials, occurring after the FDA has approved a drug for marketing, to gather additional information about a drug's safety, efficacy, or optimal use.



Please contact NeuroResearch@cuanschutz.edu or 303-724-4644 for more information

Frequently Asked Questions

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

Please contact our recruitment specialists at NeuroResearch@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 or more of these studies. What is the next step in the process?

Please contact our recruitment specialists at 303-724-4644 or NeuroResearch@cuanschutz.edu and mention the study (or studies) you are interested in. A recruitment specialist will contact you to discuss the studies further and complete brief pre-screening questionnaire(s) with you over the phone to see if you are a good fit (if applicable). If you meet the pre-screening requirements, the recruitment specialist with connect you with the coordinator who will work with you to schedule a more in-depth, in-person screening visit.

I've called or emailed Neurology Research and haven't heard back yet. How long will I have to wait?

A recruitment specialist will reach out to you via phone or email within 10 business days. Thank you in advance for your patience!

Movement Disorders

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The University of Colorado Movement Disorders Center (MDC) is a nationally recognized center for specialty care for those with movement disorders. The center is recognized as a Huntington's Disease Society of America Center of Excellence and a Parkinson's Foundation Center of Excellence. The mission of the MDC is to excel in providing world-class clinical care, conduct cutting-edge research, serve as a leader in educating professionals, and serve as a regional leader in community involvement.

	Key Eligibility Requirements
Parkinson's Disease (PD)	
Music Therapy Clinical Trial (16-2308) *Investigator:* Isabelle Buard, PhD *Purpose:* to learn more about the brain function related to fine motor skills in individuals with Parkinson's disease (PD) *Timeline:* 3-4 study visits over the course of 7 weeks and 3 sessions per week for 5 weeks for either music therapy intervention, or occupational therapy (OT) intervention, or no intervention (location options available for interventions) *Intervention:* (1) musical intervention group A, (2) musical intervention group B, (3) standard of care OT, or (4) a waitlist group for 5 weeks *ClinicalTrials.gov Identifier:* NCT03049033	• Diagnosis: PD • Age: 45-85 years old • Have some difficulties with fine motor skills (such as buttoning, cutting your food, or typing on a keyboard)
Michael J. Fox Foundation PPMI 2.0 (20-1204) *Investigator:* Michelle Fullard, MD, MSCE *Purpose:* to continue to obtain information from people with and without Parkinson's disease (PD) so that researchers may better understand how PD progresses, in order to inform better treatments *Timeline:* 2 visits annually for up to 7 years *ClinicalTrials.gov Identifier:* NCT04477785	• Diagnosis: PD for ≤ 2 years • Age: 30+ years old • NOT currently being treated with PD medications or expected to require PD medications within 6 months
SPARX3 (20-1854) *Investigator:* Cory Christiansen, PT, PhD *Purpose:* to learn more about the effects of aerobic exercise on people with Parkinson's disease (PD) who have not yet started medication for their PD *Intervention:* moderate to high intensity exercise on a treadmill *Timeline:* exercise 4x/week with periodic study visits for 24 months *ClinicalTrials.gov Identifier:* NCT04284436	• Diagnosis: PD ≤ 3 years • Age: 40-80 years old • NOT currently being treated with PD medications or expected to require PD medications within 6 months

Please contact NeuroResearch@cuanschutz.edu or 303-724-4644 for more information

Movement Disorders (cont.)

	Key Eligibility Requirements
Parkinson's Disease (PD) & Essential Tremor (ET)	
Cytokine Observational Study (18-1356) *Investigator:* Maureen Leehey, MD, FAAN *Purpose:* to learn more about the level of inflammatory and other markers in the blood of patients with PD, ET, and healthy volunteers *Timeline:* one time blood draw	• Diagnosis: PD (5-10 years since diagnosis) • Age: 60-75 years old OR • Diagnosis: ET • Age: 60-75 years old
Huntington's Disease (HD)	
Music Therapy Clinical Trial (16-2308) *Investigator:* Isabelle Buard, PhD *Purpose:* to learn more about the brain function related to fine motor skills in individuals with Huntington's disease (HD) *Timeline:* 3-4 study visits over the course of 7 weeks and 3 Neurologic Music Therapy sessions per week for 5 weeks *Intervention:* Neurologic Music Therapy (can be done at the office of a music therapist, virtually, or in home depending on location) *ClinicalTrials.gov Identifier:* NCT03049033	• Diagnosis: HD • Age: 30-85 years old • Have some difficulties with fine motor skills (such as buttoning, cutting your food, or typing on a keyboard)
Dystonia	
Dystonia Coalition Projects-3 (20-0290) *Investigator:* Jeanne Feuerstein, MD *Purpose:* This research includes four related projects each having different but overlapping goals: (1) learn about how dystonia may progress over time and what causes dystonia (Natural History project), (2) develop tools to measure the severity of symptoms objectively (Objective Measures project), (3) create a collection of blood samples for analysis (Biobank project), and (4) develop an app to monitor symptom severity (optional Patient-Centered Outcomes project) *Website:* Dystonia Coalition	• Diagnosis: any isolated focal, segmental, multifocal, generalized, or hemi-dystonia • Age: 18+ years old • For optional Patient-Centered Outcomes project: receiving Botulinum neurotoxin (BoNT) treatments as part of regular treatment plan

Movement Disorders (cont.)

	Key Eligibility Requirements
Ataxia	
FA-COMS (18-1641) *Investigator:* Trevor Hawkins, MD *Purpose:* to learn more about Friedreich ataxia (FRDA) progression and to measure clinical and biochemical changes over time *Timeline:* annual visits *ClinicalTrials.gov Identifier:* NCT03090789	• Diagnosis: Friedreich ataxia (FRDA) • Age: 18+ years old
Healthy Volunteers	
Michael J. Fox Foundation PPMI 2.0 (20-1204) *Investigator:* Michelle Fullard, MD, MSCE *Purpose:* to continue to obtain information from people with and without Parkinson's disease (PD) so that researchers may better understand how PD progresses, in order to inform better treatments *Timeline:* 2 visits annually for up to 7 years *ClinicalTrials.gov Identifier:* NCT04477785	• Have NOT been diagnosed with PD • Do NOT have a first degree relative with PD • Age: 30+ years old OR • Have NOT been diagnosed with PD • Have a first degree relative with PD • Age: 60+ years old
Cytokine Observational Study (18-1356) *Investigator:* Maureen Leehey, MD, FAAN *Purpose:* to learn more about the level of inflammatory and other markers in the blood of patients with PD, ET, and healthy volunteers *Timeline:* one time blood draw	• Have NOT been diagnosed with Parkinson's disease (PD) or essential tremor (ET) • Age: 60-75 years old

Neuro-Behavior

The University of Colorado Alzheimer's and Cognition Center is part of the School of Medicine, Department of Neurology. Their mission is to discover effective early diagnostics, preventions, treatments, and ultimately cures for Alzheimer's disease and related dementias, through research and clinical care. They believe there is as much to learn from individuals who are healthy as they do from individuals with Alzheimer's disease.

	Key Eligibility Requirements
ALLFTD (21-2833) *Investigator:* Peter Pressman, MD *Purpose:* The ARTFL LEFFTDS Longitudinal Frontotemporal Dementia (ALLFTD) study aims to evaluate sporadic (s-) and familial (f-) frontotemporal lobar degeneration (FTLD) patients and asymptomatic family members of f-FTLD patients, characterizing the cohorts longitudinally and informing clinical trial design (Biofluid-Focused and Longitudinal arms available) *ALLFTD Biofluid Timeline:* one-time visit with questionnaires, neurological exam, blood drawn, and optional lumbar puncture *ALLFTD Longitudinal Timeline:* annual visit to the clinic, each lasting 2–3 days, with questionnaires, thinking and memory questions, neurological exam, blood drawn, and an MRI *ClinicalTrials.gov Identifier:* NCT04363684	For ALLFTD Biofluid Study: • Diagnosis: FTLD syndrome like bvFTD, bvFTD with ALS, PPA, PSP, or CBD • Age: 18+ years old For ALLFTD Longitudinal Study: • Diagnosis: FTLD syndrome like bvFTD,bvFTD with ALS, PPA, PSP, or CBD • Age: 18+ years old *OR* • Are from a family with a mutation in a gene known tocause FTLD (such as C9orf72, MAPT, and GRN) • Age: 18+ years old *OR* • Have a significant family history of FTLD suggesting a familial genetic mutation • Age: 18+ years old
Conversational Speech Analysis (CSA) Study (18-0456) *Investigator:* Peter Pressman, MD *Purpose:* to learn more about how speech changes over time in adult populations, understand how those changes reflect changes in cognition, and develop new ways of detecting MCI and dementia using everyday speech *Timeline:* two study visits, one year apart *CUACC Website:* Click here	• Diagnosis: Mild cognitive impairment (MCI) or dementia *OR* Have NOT been diagnosed with a memory disorder • Age: 40-95 years old

Please contact NeuroResearch@cuanschutz.edu or 303-724-4644 for more information

Neuro-Behavior (cont.)

	Key Eligibility Requirements
Facial Expressions Study (17-0599) *Investigator:* Peter Pressman, MD *Purpose:* to understand how the brain makes different facial expressions using high speed videography, learn more about how neurological disorders may impact a person's facial movements and expressions, and develop the groundwork for a diagnostic tool that would detect differences between a person's facial movements/expressions and their emotions *Timeline:* one study visit that will last approximately one hour *CUACC Website:* Click here	• Diagnosis: Mild cognitive impairment (MCI) or dementia *OR* Have NOT been diagnosed with a memory disorder • Age: 18-75 years old • Are right handed
ImTAB (19-1423) *Investigator:* Brianne Bettcher, PhD, ABPP-CN *Purpose:* to better understand how a mild traumatic brain injury in late life relates to inflammation, markers of Alzheimer's disease related proteins, and clinical functioning over time *Timeline:* two study visits over the course of one year (a baseline and a one year follow-up visit) *Colorado Aging Brain Lab Website:* Click here	• Age: 65+ years old • In good general health • Have NOT been diagnosed with a memory disorder • Have had a concussion within the past 5 years
LIIA (18-2607) *Investigator:* Brianne Bettcher, PhD, ABPP-CN *Purpose:* to examine how inflammation and COVID-19 exposure influences brain health. Data gathered from this study will be used to better understand how inflammation may or may not disrupt thinking and memory. *Timeline:* two study visits over the course of two years *Colorado Aging Brain Lab Website:* Click here *ClinicalTrials.gov Identifier:* NCT03944603	• Age: 60+ years old • In good general health • Have NOT been diagnosed with a memory disorder • Willing to undergo 2 lumbar punctures over the course of the study

NeuroImmunology (MS)

The Rocky Mountain MS Center at the University of Colorado's cutting-edge research program — one of the largest in the world — conducts basic science, clinical trials and translational research to find effective MS treatments. The results from this work are driving our medical care approach to maximize lifelong brain health through comprehensive care, which supports the brain's ability to protect and repair itself and promotes quality of life for patients and their families. Our physicians and scientists play a critical role in the development of current and emerging MS therapies, as well as studies to determine the biological basis of the disease.

	Key Eligibility Requirements
Relapsing and Secondary Progressive Multiple Sclerosis	
ARTIOS (20-0705) *Investigator*: Enrique Alvarez, MD, PhD *Purpose*: to evaluate the safety and effectiveness of ofatumumab treatment in subjects who are transitioning from Tecfidera (dimethyl fumarate) or Gilenya (fingolimod) to ofatumumab (Kesimpta), due to breakthrough disease. *Intervention:* ofatumumab *Timeline*: 13 study visits over 96 weeks *ClinicalTrials.gov Identifier:* NCT04353492	• Age: 18-60 years old • Diagnosis: relapsing MS • Currently taking Gilenya (fingolimod) or Tecfidera (dimethyl fumarate)
BEAT-MS (19-1621) *Investigator*: John Corboy, MD *Purpose*: to compare efficacy and safety of autologous hematopoietic stem cell transplantation (AHSCT) to best available therapy (BAT) in treatment resistant relapsing MS. *Intervention:* best available therapy (50% chance) or AHSCT cell transplant (50% chance) *Timeline*: up to 17 study visits over 6 years (not including stem cell transplantation procedures, if randomized to AHSCT group) *ClinicalTrials.gov Identifier:* NCT04047628	• Age: 18-55 years old • Diagnosis: highly active, treatment resistant MS • 2 clinically confirmed episodes of treatment failure in the past 36 months • Insurance or public funding available to cover the cost of an MS DMT
CAVS-MS (20-1000) *Investigator*: Enrique Alvarez, MD, PhD *Purpose*: to assess the utility of the central vein sign to diagnose MS to avoid delay in initiating treatment. The central vein depicts small veins in your brain around which MS changes are centered. *Timeline:* 3 study visits over 2 years *ClinicalTrials.gov Identifier:* NCT04495556	• Age: 18-65 years old • Recently diagnosed with MS or with suspected MS

Please contact NeuroResearch@cuanschutz.edu or 303-724-4644 for more information

Neuro-Immunology (cont.)

	Key Eligibility Requirements
DELIVER-MS (18-1633) *Investigator*: Enrique Alvarez, MD, PhD *Purpose*: to learn whether there is a difference between two common treatment approaches for people who have recently been diagnosed with relapsing remitting MS: escalation approach (start out by using a lower-risk, moderately effective medication) vs early highly effective treatment approach (start out with one of the stronger, but potentially more risky, medications). *Timeline*: 13 study visits over 3 years *ClinicalTrials.gov Identifier:* NCT03535298	• Age: 18-60 years old • Recently diagnosed with MS • Not currently taking any MS medication (but plan to start one soon)
ENLIGHTEN (19-2420) *Investigator*: Amanda Piquet, MD *Purpose*: to learn about changes in cognition that happen while being treated with the medication RPC1063, also known as ozanimod, taken by mouth in the treatment of RMS. *Timeline*: 13 study visits over 3 years *Intervention:* ozanimod *Clinicaltrials.gov Identifier:* NCT04140305	• Age: 18-65 years old • Diagnosis: relapsing MS (diagnosed ≤ 5 years ago) • Treatment history of 0-1 MS medications
FENhance (20-3036) *Investigator*: Enrique Alvarez, MD, PhD *Purpose*: The purpose of this study is to compare the effects, good or bad, of fenebrutinib versus teriflunomide (Aubagio) on subjects with relapsing MS. *Intervention:* Fenebrutinib (50% chance) or Aubagio (50% chance) *Timeline*: 14 visits over 96 weeks *ClinicalTrials.gov Identifier:* NCT04586023	• Age: 18-55 years old • Diagnosis: relapsing MS or active secondary progressive MS • Recent disease activity (new lesion or relapse in past year)
OLIKOS (20-2135) *Investigator*: Enrique Alvarez, MD, PhD *Purpose*: to find out if patients that are switched to ofatumumab (Kesimpta) from intravenous Ocrevus or Rituxan for reasons other than efficacy or safety reasons continue to show efficacy after being switched. *Intervention:* Kesimpta *Timeline:* 5 study visits over 14 months *ClinicalTrials.gov Identifier:* NCT04486716	• Age: 18-60 years old • Diagnosis: relapsing MS • Received a dose of Ocrevus or Rituxan in past 9 months but planning to switch to Kesimpta for reasons other than safety or efficacy

Neuro-Immunology (cont.)

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	Key Eligibility Requirements
Primary Progressive Multiple Sclerosis	
ATA188 (20-0454) *Investigator*: Enrique Alvarez, MD, PhD *Purpose*: to evaluate the safety and efficacy of the investigational drug ATA188. *Intervention:* year 1: ATA188 (50% chance) or placebo (50% chance), years 2-5: ATA188 (no placebo) . *Timeline*: 63 study visits over 5 years (weekly visits at first, then quarterly as trial continues) *ClinicalTrials.gov Identifier:* NCT03283826	• Age: 18-60 years old • Diagnosis: non-active (no recent relapses) progressive form of MS • Willing to undergo 4 lumbar punctures over 5 year trial • Willing to discontinue current MS treatment
FENtrepid (21-2663) *Investigator*: Enrique Alvarez, MD, PhD *Purpose*: to compare the effects, good or bad, of fenebrutinib versus ocrelizumab (Ocrevus) on subjects with primary progressive MS. *Intervention:* Fenebrutinib (50% chance) or Ocrevus (50% chance) *Timeline*: 16 visits over 120 weeks *ClinicalTrials.gov Identifier:* NCT04544449	• Age: 18-65 years old • Diagnosis: primary progressive MS • Able to walk 25 feet
High Dose Ocrevus (20-1853) *Investigator*: Enrique Alvarez, MD, PhD *Purpose*: to compare the effects, good or bad, of a higher dose of ocrelizumab versus the approved dose of ocrelizumab on participants with progressive MS. *Intervention:* Higher dose of Ocrevus (66% chance) or approved dose of Ocrevus (33% chance) *Timeline*: 12 visits over 120 weeks *ClinicalTrials.gov Identifier:* NCT04548999	• Age: 18-55 years old • Diagnosis: primary progressive MS
Exercise Studies	
PT-MS (20-1527) *Investigator*: Mark Manago, DPT, PhD, PT, NCS *Purpose*: to learn more about the effects of strength training on walking in people with MS. *Intervention:* strength training exercises *Timeline*: 14 study visits over 22 weeks (includes a 10 week exercise program) *ClinicalTrials.gov Identifier:* NCT04548154	• Age: 18-70 years old • Diagnosis: MS • Able to walk 100 meters without assistance

Neuro-Immunology (cont.)

	Key Eligibility Requirements
Blood Flow Restriction (20-0965) *Investigator*: Mark Manago, DPT, PhD, PT, NCS *Purpose*: to determine the feasibility of physical therapy strengthening exercises using blood flow restriction (BFR) in people with MS who have moderate-to-severe walking problems. *Intervention:* blood flow restriction training *Timeline:* 2 study visits per week for 8 weeks *ClinicalTrials.gov Identifier:* NCT04633759	• Age: 18-65 years old • Diagnosis: MS • Must rely on assistance to walk OR use self-propelled wheelchair
Healthy Volunteer Studies	
DREAMS (19-0393) *Investigator*: Teri Schreiner, MD, MPH *Purpose*: to learn more about the risk factors for and causes of MS by studying children who are first degree relatives of people with MS. *Timeline*: a single 3-4 hour study visit (includes MRI and blood draw)	• Age: 10-17 years old • Have parent or sibling with MS • No diagnosis of MS or early symptoms of MS
RISEMS (17-1884) *Investigator*: Enrique Alvarez, MD, PhD and John Corboy, MD *Purpose*: to learn more about the risk factors for and causes of MS by studying first degree relatives of people with MS *Timeline*: a single 2-3 hour study visit (includes MRI and blood draw) *ClinicalTrials.gov Identifier:* NCT03586986	• Age: 18-30 years old • Have a parent, sibling or child with MS • No diagnosis of MS or early symptoms of MS
Booster Study (21-4092) *Investigator*: Amanda Piquet, MD *Purpose*: to better understand Covid19 vaccine response in patients with certain neurological conditions who are taking medicines that suppress the immune system. *Timeline*: up to 5 blood draws over 1 year	• Age 18-89 years old • Already received first 2 doses of COVID vaccine

NeuroMuscular

The Neuromuscular Division provides care for a large and diverse group of rare diseases including Amyotrophic Lateral Sclerosis (ALS), Muscular Dystrophies, Myasthenia Gravis, inherited neuropathies, and many others. We are a quaternary care center meaning we handle the highest level of complexity in medical care, and we are a Muscular Dystrophy Association Care Center providing weekly multi-disciplinary care clinics. The goal of the Neuromuscular Clinical Research Program is to help patients with neuromuscular diseases in the Rocky Mountain Region gain access to cutting-edge therapies.

	Key Eligibility Requirements
Charcot Marie Tooth Disease (CMT)	
Natural History Evaluation (18-2537) *Investigator*: Vera Fridman, MD *Purpose*: observational, longitudinal study to determine natural history and genotype-phenotype correlations of disease causing mutations in Charcot Marie Tooth disease (CMT) *ClinicalTrials.gov Identifier:* NCT01193075	• Diagnosis: CMT *or* have a relative with CMT
Genetics of CMT (20-1525) *Investigator*: Vera Fridman, MD *Purpose*: to look for new genes that cause Charcot Marie Tooth disease (CMT) and to look for genes that don't cause CMT, but may modify the symptoms a person has *ClinicalTrials.gov Identifier:* NCT01193088	• Diagnosis: CMT *or* have a relative with CMT
TTR Amyloidosis	
THAOS (08-0623) *Investigator*: Dianna Quan, MD *Purpose*: to follow patients with transthyretin amyloidosis (ATTR) over time and gather information about the disease process to lead to better treatment *ClinicalTrials.gov Identifier:* NCT00628745	• Age: 18+ years old • Diagnosis: TTR amyloidosis

Neuromuscular (cont.)

	Key Eligibility Requirements
Amyotrophic Lateral Sclerosis (ALS)	
COURAGE–ALS (21-2598) *Investigator*: Dianna Quan, MD *Purpose*: to evaluate the efficacy and safety of reldesemtiv as a possible treatment for the improvement of skeletal muscle function in conditions associated with muscle weakness or fatigue such as ALS *Intervention:* reldesemtiv (66% chance) or placebo (33% chance) for first 24 weeks but everyone will receive reldesemtiv for the next 24 weeks *Timeline:* 8 in person study visits over 52 weeks *ClinicalTrials.gov Identifier:* NCT04944784	• Age: 18-80 years old • Diagnosis: ALS • Onset of ALS symptoms less than 24 months ago • Able to swallow pills
Oral Edaravone (20-2340) *Investigator*: Stacy Dixon, MD, PhD *Purpose*: to test if an experimental drug called edaravone (Radicava) is effective and safe and to compare its effects when it is given in 2 different ways. *Intervention:* oral form of edaravone, taken daily for 28 days (50% chance) or taken daily for 14 days followed by 14 days of placebo (50% chance) *Timeline*: 8 in person visits over 58 weeks *ClinicalTrials.gov Identifier:* NCT04569084	• Age: 18-75 years old • Diagnosis: ALS • Onset of ALS symptoms less than 2 years ago • No previous treatment with edaravone
REFINE-ALS (19-1560) *Investigator*: Laura Foster, MD *Purpose*: to learn what changes happen in patients with Amyotrophic Lateral Sclerosis (ALS) that can be seen in the blood and urine when they take edaravone (Radicava). These changes are called biomarkers. *Timeline:* 8 study visits over 24 weeks *ClinicalTrials.gov Identifier:* NCT04259255	• Age: 18+ years old • Diagnosis: ALS • Planning to start edaravone (Radicava) or received first dose within last 28 days
Myasthenia Gravis (MG)	
MINT (20-1787) *Investigator*: Dianna Quan, MD *Purpose*: to determine whether the investigational drug inebilizumab is safe and effective in reducing the symptoms of myasthenia gravis *Intervention:* inebilizumab (50% chance) or placebo (50% chance) *Timeline:* up to 12 visits over up to 13 months (depends on what type of MG you have), open label extension available *Clinicaltrials.gov Identifier:* NCT04524273	• Age: 18+ years old • Diagnosis: AChR or MuSK myasthenia gravis • Currently taking (1) corticosteroids, (2) non-steroidal IST or a combination of the 2

Neuromuscular (cont.)

	Key Eligibility Requirements
Myasthenia Gravis (MG) cont.	
Vivacity MG3 (21-3289) *Investigator*: Dianna Quan, MD *Purpose*: to see if nipocalimab is safe and useful for treating adults with generalized myasthenia gravis. *Intervention:* nipocalimab infusion (50% chance) or placebo (50% chance). *Timeline:* 13 visits over 24 weeks, (includes infusion every 2 weeks) open label extension available *Clinicaltrials.gov Identifier:* NCT04951622	• Age: 18+ years old • Diagnosis: myasthenia gravis with generalized muscle weakness
Facioscapulohumeral Muscular Dystrophy (FSHD)	
MOVE FSHD (20-0405) *Investigator*: Matthew Wicklund, MD *Purpose*: to collect motor and functional outcomes specific to facioscapulohumeral muscular dystrophy (FSHD) over time to ensure the best level of clinical care and to speed up drug development by gaining a better understanding of how having FSHD impacts motor function and other health outcomes *Timeline*: 1 study visit per year for 3 years *ClinicalTrials.gov Identifier:* NCT04635891	• Diagnosis: FSHD Type 1 or 2, genetically confirmed or family history and functionally affected
Limb Girdle Muscular Dystrophy (LGMD)	
LGMD GRASP (19-0506) *Investigator*: Matthew Wicklund, MD *Purpose*: to learn more about limb girdle muscular dystrophy (LGMD) by measuring how your muscles change over time. *Timeline:* 4-5 study visits over 12 months *ClinicalTrials.gov Identifier:* NCT03981289	• Age: 4-65 years old • Diagnosis: clinically affected LGMD (weakness in limb girdle pattern or in distal extremity)

NeuroHospitalists (Stroke)

We do not have any studies currently enrolling via advertising, but there may be studies enrolling via provider referral. If you have questions about this or if you would like to be contacted about future neurohospitalist studies, please contact NeuroResearch@cuanschutz.edu or 303-724-4644.

Epilepsy

Studies are currently being enrolled through the Epilepsy/Neuro-Diagnostics Clinical Practice at Anschutz Medical Campus. However, if you would like to be contacted about future epilepsy studies, please contact NeuroResearch@cuanschutz.edu or 303-724-4644.

Headache

We do not have any enrolling studies in this subspecialty right now. However, if you would like to be contacted about future headache studies, please contact NeuroResearch@cuanschutz.edu or 303-724-4644.

NeuroOphthalmology

Studies are currently being enrolled through UCH admissions. However, if you would like to be contacted about future neuro-ophthalmology studies, please contact NeuroResearch@cuanschutz.edu or 303-724-4644.

Healthy Volunteers

Anschutz

These studies are for people with no known neurological conditions. Healthy volunteer studies provide crucial data for our researchers by creating a comparison group for neurological conditions and by helping us learn more about how the brain typically functions when unaffected by disease. These studies are a great opportunity for people with no neurological conditions to contribute to the field of neurology research.

	Key Eligibility Requirements
Movement Disorders	
Michael J. Fox Foundation PPMI 2.0 (20-1204) *Investigator:* Michelle Fullard, MD, MSCE *Purpose:* to continue to obtain information from people with and without Parkinson's disease (PD) so that researchers may better understand how PD progresses, in order to inform better treatments *Timeline:* 2 visits annually for up to 7 years *ClinicalTrials.gov Identifier:* NCT04477785	• Have NOT been diagnosed with PD • Do NOT have a first degree relative with PD • Age: 30+ years old OR • Have NOT been diagnosed with PD • Have a first degree relative with PD • Age: 60+ years old
Cytokine Observational Study (18-1356) *Investigator:* Maureen Leehey, MD, FAAN *Purpose:* to learn more about the level of inflammatory and other markers in the blood of patients with PD, ET, and healthy volunteers *Timeline:* one time blood draw	• Have NOT been diagnosed with Parkinson's disease (PD) or essential tremor (ET) • Age: 60-75 years old
Neuro-Behavior	
ImTAB (19-1423) *Investigator:* Brianne Bettcher, PhD, ABPP-CN *Purpose:* to better understand how a mild traumatic brain injury in late life relates to inflammation, markers of Alzheimer's disease related proteins, and clinical functioning over time *Timeline:* two study visits over the course of one year (a baseline and a one year follow-up visit) *Colorado Aging Brain Lab Website:* Click here	• Age: 65+ years old • In good general health • Have NOT been diagnosed with a memory disorder • Have had a concussion within the past 5 years

Please contact NeuroResearch@cuanschutz.edu or 303-724-4644 for more information

	Key Eligibility Requirements
LIIA (18-2607) *Investigator:* Brianne Bettcher, PhD, ABPP-CN *Purpose:* to examine how inflammation and COVID-19 exposure influences brain health. Data gathered from this study will be used to better understand how inflammation may or may not disrupt thinking and memory. *Timeline:* two study visits over the course of two years *Colorado Aging Brain Lab Website:* Click here *ClinicalTrials.gov Identifier:* NCT03944603	• Age: 60+ years old • In good general health • Have NOT been diagnosed with a memory disorder • Willing to undergo 2 lumbar punctures over the course of the study
Neuro-Immunology (MS)	
DREAMS (19-0393) *Investigator*: Teri Schreiner, MD, MPH *Purpose*: to learn more about the risk factors for and causes of MS by studying children who are first degree relatives of people with MS. *Timeline*: a single 3-4 hour study visit (includes MRI and blood draw)	• Age: 10-17 years old • Have parent or sibling with MS • No diagnosis of MS or early symptoms of MS
RISEMS (17-1884) *Investigator*: Enrique Alvarez, MD, PhD and John Corboy, MD *Purpose*: to learn more about the risk factors for and causes of MS by studying first degree relatives of people with MS *Timeline*: a single 2-3 hour study visit (includes MRI and blood draw) *ClinicalTrials.gov Identifier:* NCT03586986	• Age: 18-30 years old • Have a parent, sibling or child with MS • No diagnosis of MS or early symptoms of MS
Booster Study (21-4092) *Investigator*: Amanda Piquet, MD *Purpose*: to better understand Covid19 vaccine response in patients with certain neurological conditions who are taking medicines that suppress the immune system. *Timeline*: up to 5 blood draws over 1 year	• Age 18-89 years old • Already received first 2 doses of COVID vaccine

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Department of Neurology