



Currently Enrolling Biofluid Biomarker Studies

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Why are biofluid biomarker studies important for ALS Research?

Biofluid biomarkers are measurable changes in your body that can be observed in your blood, urine, and cerebral spinal fluid. These changes can indicate healthy or unhealthy processes happening in your body and may be a sign of an underlying condition or disease such as ALS.

Researchers conduct biomarker research to measure the effects of investigational drugs on people during clinical trials. Biofluid biomarkers are an integral part of this research and may:

- Lead to earlier diagnosis of ALS or other neurodegenerative diseases
- Predict and track disease progression more efficiently
- Demonstrate whether an investigational drug reaches its designated target
- Identify subsets of people who best respond to a certain investigational drug

Biofluid biomarker studies provide an opportunity for all people with ALS to participate in research and make important contributions to our scientific understanding of ALS.

Study of Longitudinal Microbiome in ALS

Enroll and participate from your home!

Full Study Name: Longitudinal Assessment of the Gut Microbiome in People with ALS

Study Length: 5 years Participants: People with ALS, asymptomatic ALS gene carriers,

healthy volunteers

Biomarkers: Stool and blood

samples

Purpose: To collect and analyze stool samples and observe the relationship between the gut microbiome and the progression of ALS over time. Information collected in this study will further our understanding of ALS and contribute Collaborating researchers will have towards the development of novel therapeutics.

Principal Investigator: James Berry, MD, MPH

Sponsor: National Institutes of Health and Brigham and Women's Hospital

Enrollment Contact:

Ethan Riddell, 617-643-4803, eriddell@mgh.harvard.edu; Jane Lim, 617-643-7828, jlim19@mgh.harvard.edu

Target ALS Biomarker Study

Coming Soon!

Full Study Name: Target ALS Biomarker Study: Longitudinal Biofluids, Clinical Measures, and At-Home Measures

Study Length: 16 months for ALS participants, 12 months for healthy volunteers

Participants: ALS and Healthy Volunteers able to have lumbar

punctures Biomarkers: Blood, spinal fluid, urine **Purpose:** The goal of the study is to

build a library of samples (blood, cerebral spinal fluid, and urine) and linked medical and genetic data. access to this information to advance

their knowledge of ALS. Principal Investigator: Mark Garret,

MD

Sponsor: Target ALS **Enrollment Contacts:** Lily Walker, 617-643-7909, lgwalker@mgh.harvard.edu; Jane Lim, 617-643-7828, jlim19@mgh.harvard.edu

For more information:

Contact the research coordinator(s) listed for studies you are interested in OR Judi Carey, Research Access Nurse, mghalsresearchemgh.harvard.edu or 617-724-8995

Study of LAB PALS

Full Study Name: A Longitudinal Analysis of

Biomarkers in Patients with ALS

Study Length: 4 years (16 in-person visits)

Participants: People with ALS, asymptomatic ALS gene carriers, non-ALS neurological disease, healthy

volunteers

Biomarkers: Blood, urine, and cerebrospinal fluid **Purpose:** We would like to see how biomarkers and cerebrospinal fluid (optional) change over time in people with ALS. A biomarker is a molecule that we can measure to diagnose or monitor a disease.

Principal Investigator: James Berry, MD, MPH

Sponsor: ALS Finding a Cure

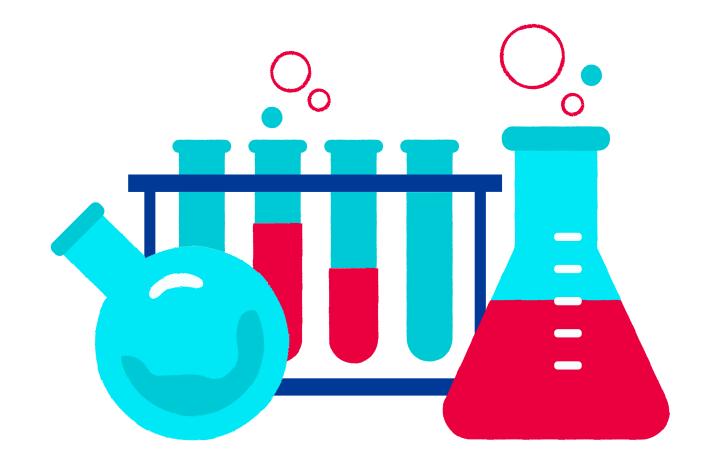
Enrollment Contacts:

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617-724-7113



Study of DIALS

Full Study Name: Dominant Inherited ALS (DIALS)

Network

Study Length: At least 5 years (annual visits with

optional 6-month visits)

Participants: People who do not have any neurological symptoms,

but have a first-degree relative with ALS caused by a

mutation

Biomarkers: Blood, urine, and optional cerebrospinal

fluid

Purpose: To study people at risk for developing ALS to further our understanding of underlying early disease changes. The information collected in this study may lead to development of treatments that target the earliest changes in ALS and allow for possible disease prevention.

Principal Investigator: James Berry, MD, MPH **Sponsor:** ALS Finding a Cure, ALS Association,

Philanthropy

Enrollment Contacts: <u>DIALS@mgh.harvard.edu</u>, or

call Gavi Forman at 617-724-7928

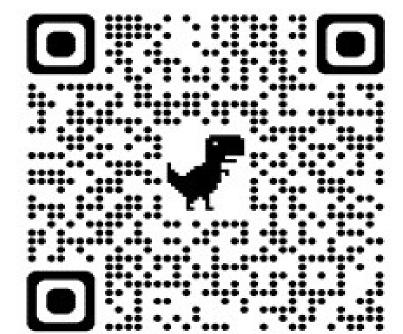
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