

# Currently Enrolling Biofluid Biomarker Studies

## 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 ASSESS ALL ALS

**Full Study Name:** ASSESS ALL ALS – Longitudinal Biomarker Study for Symptomatic ALS and Healthy Control Participants

**Study Length:** up to 2 years (7 in-person or remote visits)

**Participants:** People with ALS and healthy volunteers

**Biomarkers:** Blood

**Purpose:** To study people diagnosed with ALS and healthy participants to further our understanding of the disease and potential biomarkers of disease progression. The information collected in this study may contribute to future research and development of new treatments for ALS and similar neurological diseases.

**Principal Investigator:** James Berry, MD, MPH

**Sponsor:** National Institutes of Health and St. Joseph's Hospital and Medical Center, Phoenix, AZ

**Enrollment Contacts:**

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Aisling Finnegan at 617-726-1880

## Study of Target ALS Biomarker

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

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

**Participants:** ALS and Healthy Volunteers who are able to have lumbar punctures\*

**Biomarkers:** Blood, spinal fluid, urine  
**Purpose:** Build a library of samples (blood, cerebral spinal fluid, and urine) and linked medical and genetic data. Collaborating researchers will have access to this information to advance their knowledge of ALS.

**Principal Investigator:** James Berry, MD, MPH

**Sponsor:** Target ALS

**Enrollment Contact:**

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Scan to learn more about the lumbar puncture procedure.

<https://shorturl.at/6exoH>



## For more information:

Contact the research coordinator(s) listed for studies you are interested in OR Judi Carey, Research Access Nurse, [mghalsresearch@mgh.harvard.edu](mailto:mghalsresearch@mgh.harvard.edu) or 617-724-8995

## Study of LABPALS

**Full Study Name:** A Longitudinal Analysis of Biomarkers in Patients with ALS

**Study Length:** up to 4 years; approximately 16 in-person visits

**Participants:** People with ALS, asymptomatic ALS gene carriers, people with other neurological diseases, and 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

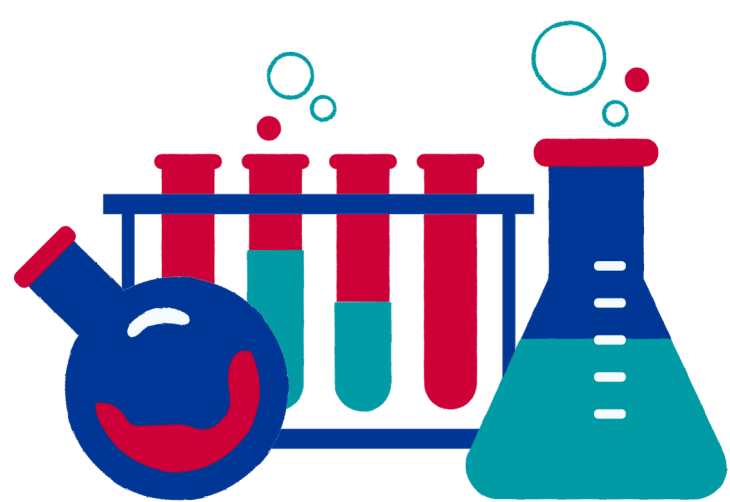
**Sponsor:** ALS Finding a Cure

**Enrollment Contacts:**

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## Study of PREVENT ALL ALS

**Full Study Name:** PREVENT ALL ALS – Longitudinal Biomarker Study for Participants Who Are At Risk for ALS

**Study Length:** up to 3 years (6 remote visits/3 yearly in-person visits)

**Participants:** People who are asymptomatic ALS gene carriers or have a family history of ALS

**Biomarkers:** Blood and optional cerebrospinal fluid collection

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

**Principal Investigator:** James Berry, MD, MPH

**Sponsor:** National Institutes of Health and St. Joseph's Hospital and Medical Center, Phoenix, AZ

**Enrollment Contacts:**

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## 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:** Up to 5 years

**Participants:** People with ALS, asymptomatic ALS gene carriers, healthy volunteers

**Biomarkers:** Stool and blood samples

**Purpose:** 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 enhance our understanding of ALS and contribute towards the development of new treatments.

**Principal Investigator:** James Berry, MD, MPH

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

**Enrollment Contact:**

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Mia Fleischer at 617-724-5659

## Stay Connected to ALS Research at the Healey Center

[Sign up for the MGH ALS Link to Stay Connected to Research:](https://lp.constantcontactpages.com/su/saTzwlp/ALSLink)



<https://lp.constantcontactpages.com/su/saTzwlp/ALSLink>

[Register for Healey Community Webinars for Updates:](https://partners.zoom.us/webinar/register/WN_JW9rQBhTRFW5uoUIDtjguw#/registration)



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[View All ALS Clinical Research at the Healey Center:](https://www.massgeneral.org/neurology/als/research/als-clinical-trials)



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