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# Sophisticated Staff Coordinates ALLFTD Study

*Meet Program Managers Dr. Leah Forsberg, Mayo, and Dr. Hilary Heuer, UCSF*

Unlimited cell phone plans are a must for the two program managers who are charged with overseeing the day-to-day operation of the new ALLFTD Study, especially since each resides in a different time zone and the study's sites span the United States and Canada.

As **ALLFTD** program managers, Leah Forsberg, Ph.D., with Mayo Clinic in Rochester, Minnesota, and Hilary Heuer, Ph.D., with University of California, San Francisco (UCSF), together serve as the linchpin that connects the various parts of the study so it functions as a unit. They coordinate between the study's **principal investigators** (also known as the study PIs) who oversee the entire research project, and each site's study team including its PI, **study coordinator**, and other team members.

"As part of the ALLFTD Executive Team we coordinate with different parts of the ALLFTD team to make decisions about how the study should be conducted, and then Leah and I attempt to implement those decisions," Dr. Heuer explained. "Our study responsibilities overlap quite a bit, but we each have certain components of ALLFTD management that we primarily manage."

In the search for answers to treatments and a cure for **frontotemporal lobar degeneration** (FTLD), it takes many dedicated people serving in a variety of roles to set up, oversee, and administer the new multisite cooperative ARTFL-LEFFTDS Longitudinal Frontotemporal Lobar Degeneration Study, more commonly called ALLFTD.

A **research consortium**, ALLFTD merges Advancing Research and Treatment in Frontotemporal Lobar Degeneration (ARTFL) and Longitudinal Evaluation of Familial Frontotemporal Dementia Subjects (LEFFTDS) to create a network of 19 centers in North America that are committed to FTLD research. This extensive research consortium is made up of world experts on FTLD, led by the three ALLFTD PIs: Dr. Brad Boeve, Mayo Rochester, and Dr. Adam Boxer and Dr. Howard "Howie" Rosen, UCSF. Its aim is to advance understanding of FTLD and support the development of treatments for these progressive neurodegenerative disorders.

***A glossary is available to help you understand the scientific terms used in this article. Glossary terms are shown in bold the first time they appear.***

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Each study location has at least one site PI and a study coordinator, but most sites have a team of staff who play a large role in making the study successful at their site. "At most sites it's up to the study coordinators to work with their site PI to implement the study requirements at their facility," Dr. Forsberg explained.

## Incorporating the Old and the New

Because ALLFTD is an extension of ARTFL and LEFFTDS, any previous ARTFL or LEFFTDS study participant will be encouraged to continue participating in research by joining ALLFTD. Site facilities, visits, and staff will mostly remain the same from the previous two FTLD research studies. Some sites have new staff and study coordinators who are learning about FTLD research for the first time while other sites have seasoned personnel.

"All of the study coordinators are incredible, with varying degrees of experience and familiarity with FTLD. We're really lucky to have such a great group of coordinators working on this study," said Dr. Forsberg.

"Many of the ALLFTD study procedures are similar (to the ARTFL/LEFFTDS studies)," noted Dr. Heuer, "but we've added some new study elements that we're really excited about. For example, **cognitive testing**, which we used to do on a laptop computer, is now going to be done on a tablet. I think that our research participants will like the new versions of these cognitive tests."

ALLFTD participants will have a **neurological exam** with a clinician, tests of memory and thinking, brain imaging, blood draw, and questionnaires for the participant and their study partner to complete. Dr. Heuer explains, "all of these different components add up, so it's not uncommon for a visit to last multiple days." Each visit is between two to four days depending on


the site availability, resources and scheduling. For example, study coordinators must find and schedule available rooms that the clinician or ALLFTD team member need for each visit procedure.

Many of the visit-specific details are determined by the structure of a site as well as the site investigator. At some locations the primary investigator is solely working on the ALLFTD study, and at others the PI may be involved with multiple studies and have several support staff personnel to assist them.

"Each site has a flow that works really well for them," said Dr. Forsberg. "We don't mandate that things happen in a specific order so that each site can conduct the visit in a way that works best for them. This can make managing the study challenging because each site is different, especially because we want to provide consistent guidance on how visit procedures should be done so we're all collecting data similarly. More often than not it's a fun challenge; and as long as we understand how things work at each site, we can figure it out so the study runs smoothly and consistently."

## Study Coordinators

The study coordinator's routine can vary greatly from day to day, but typically it involves interaction with participants, whether recruiting, scheduling, or con-

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ducting in-person visits. After each study visit there are quite a few tasks needed to finish the visit, including data entry, payment for travel or participation, and following up with study partners.

Study coordinator responsibilities vary by site, adding to the complexity of coordinating this large research study. For example, at Mayo Rochester the study coordinators are supported by associate clinical research coordinators who help with the scheduling, data entry and see participants (especially when there is a family at the clinic for their research visit) and **psychometrists** who do the memory and thinking tests.

"However, at Mayo Jacksonville the study coordinator does the job duties listed above and administers the memory and thinking tests," Dr. Forsberg said. "Each site has a different number of study staff assisting with each study visit, both pre- and post- visit activities."

"At UCSF the study coordinators do all of the scheduling themselves as well as help with administering tests," Dr. Heuer explained.

"Even if their responsibilities vary by site, the ALLFTD study coordinators work to make the whole visit flow smoothly for the participant," she said. "They are a busy group, and we couldn't do it without them."

## Program Managers

The program managers are a busy pair, too.

Dr. Forsberg earned her degree in medicinal chemistry before transitioning from bench work to clinical research. She started her ALLFTD career as a research coordinator working on ARTFL and LEFFTDS, and then moved into her role as an ALLFTD project manager.

Dr. Heuer's degree in **neurophysiology**, and ocular motor control led her into the FTLD field to work on eye movement deficits in persons affected by **progressive supranuclear palsy** (PSP). She continues to be involved in eye movement research while she serves as an ALLFTD project manager.

"It's really exciting to me that I am working on something clinically important for people impacted by FTLD," Dr. Heuer said. "While I'm not directly working with them, I'm doing something that could eventually make people's lives better."

While neither scientist will see ALLFTD participants on a regular basis, they do interact with people who reach out through the study's website: https://www.allftd.org. In addition, they contribute to writing and administering grants and coordinating with all of the ALLFTD study teams and scientific researchers.

Dr. Heuer works more with the investigators, data management, and data quality issues; Dr. Forsberg focuses her efforts on working with the study coordinators and other staff on day-to-day operations and visit procedures.

"Generally, I think we have a fantastic working relationship," Dr. Forsberg said. "It has been easy to identify our strengths and to tailor our management of the study appropriately."

When asked how long they have been working together, Dr. Heuer laughed when Dr. Forsberg quickly replied, "Forever." What may seem like forever, has only been about three years. Dr. Heuer's involvement with ARTFL started with the grant proposal (study inception) in late 2013, and shortly thereafter she began working on LEFFTDS. Dr. Forsberg joined the ARTFL and LEFFTDS team at the Mayo Clinic in Rochester in late 2017.

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In addition to the numerous phone calls and emails, teleconferencing has boosted the duo's productivity. Scheduling can be a challenge since they work in different time zones. Dr. Heuer is located in California, and Dr. Forsberg is now based in Colorado.

"We've found a really nice management rhythm, which involves multiples phone calls a day generally focused on who will address an issue or tackle which to-do list items and what hikes we plan to do the next weekend (well pre-COVID that is)," commented Dr. Forsberg.

## The Future with ALLFTD

They are both excited about ALLFTD and the new study features. For example, ALLFTD will follow all participants annually (**longitudinally**), previously only those with a family history of FTLD were seen annually. Additionally, there will be more comprehensive **biospecimen** research analyses.

"We've already learned a lot about **neurofilament**, which is a protein in plasma that indicates **neurodegeneration**," Dr. Heuer said. "We will be learning a lot about different **biomarkers** in ALLFTD. Identifying new biomarkers, both **biofluid** and **imaging markers**, are a main reason we're doing this study because they will hopefully lead to new **therapeutic** treatments in the near future."

ALLFTD has a robust data analysis planned, analyzing more biomarkers than previous studies. These scientific analyses will help answer questions such as: What (biomarker) can be measured that might indicate disease onset or progression? What are possible targets for disease modification?

"It's exciting to have ARTFL and LEFFTDS combined in order to do more longitudinal research. This allows us to see rates of progression, and learn more about what might influence those rates of progression," Dr. Heuer said. "We can also learn about disease onset in families with (**gene**) **mutations**. It's wonderful to have so much data coupled with a wealth of experience from some of the best FTLD researchers in the country."

"We are really lucky to work on this project and be surrounded by, I think, the best FTLD researchers, whether they are seeing participants or carrying out the bench research. Everybody is contributing to ALLFTD," Dr. Forsberg stated. "I think the leadership that we get from the three study PIs is really amazing. They've done a lot of really hard work to get us to this point, and will continue to work hard as the leaders of ALLFTD."

"Add to that, all the site PIs and study teams are really committed; we're so grateful to have such incredible study personnel," she said.

Dr. Heuer concurred with the assessment. "One of the really impressive things about this consortium is getting so many really excellent researchers to come together to work on a project like this, it's amazing," Dr. Heuer said. "And they are all incredibly caring clinicians and physicians as well."

While it takes a sophisticated staff to operate all of the facets of the new study, it is the people affected by

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FTLD who take the time to visit the sites, participate in research, and contribute to science who make this all possible.

"We really appreciate the commitment to research from our participants. Choosing to participate in ALLFTD study is a large time commitment. And their willingness to do it year after year is really amazing," noted Dr. Forsberg. "We can dream up all the cool scientific questions, but without their support, the research doesn't happen. We're grateful and excited to have them participate."

About 125 people attended the ALLFTD Team Meeting last fall. Their titles and job descriptions included:

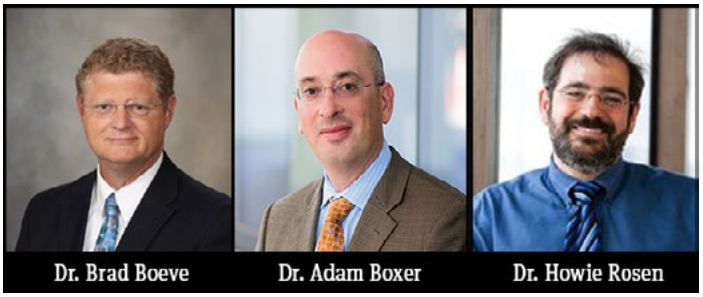
- Study PIs
- Site PIs
- Project Managers
- Study Coordinators
- **Neuropsychologists**
- Psychometrists
- **Genetic Counselors**
- **Neuroimaging Specialists**
- Biospecimen Teams (NCRAD = National Centralized Repository for Alzheimer's Disease and Related Dementias)
- Research Core Team Leads and Members

**Read about the ALLFTD Study**

**See a list of study sites, site principal investigators, and site study coordinators**

**View the Glossary**

## ALLFTD Study Principal Investigators (PIs)




The ALLFTD study is co-directed by Dr. Bradley "Brad" Boeve at the Mayo Clinic in Rochester, Minnesota, and Dr. Adam Boxer and Dr. Howard "Howie" Rosen, both at the University of California, San Francisco (UCSF).

## Dr. Brad Boeve

Bradley F. Boeve, M.D., is a professor of neurology with College of Medicine and Science and a consultant in the Department of Neurology and Center for Sleep Medicine at Mayo Clinic in Rochester, Minnesota.

His clinical and research interests include normal aging, neurodegenerative disorders that cause cognitive impairment or dementia, neurogenetics, prion disorders, and neurological sleep disorders. Focus areas are FTLD, Lewy body disease (LBD), REM sleep behavior disorder (RBD), and Alzheimer's disease.

Specific areas of interest include mild cognitive impairment, Pick's disease, primary progressive aphasia (PPA), corticobasal degeneration (CBD), progressive supranuclear palsy (PSP), posterior cortical atrophy (PCA). He also has interests in neurologically based sleep disorders such as narcolepsy, Creutzfeldt-Jakob disease, restless legs syndrome, and periodic limb movement disorder.

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Dr. Boeve hopes that through his research, better tools will be developed to predict those individuals who will develop a neurodegenerative disease, diagnose individuals as early as possible, and more optimally treat symptoms. He is particularly interested in how treatments can be used to slow down the rate of progression, delay the onset, or prevent the development of dementia and parkinsonism.

In addition to his primary roles at Mayo Clinic, Dr. Boeve serves as director of the Division of Behavioral Neurology and co-director of the Clinical Core of the Alzheimer's Disease Research Center. He joined the Mayo Clinic staff in 1997 and is the Little Family Foundation Professor of Lewy Body Dementia.

His professional highlights include serving as co-principal investigator of the Longitudinal Evaluation of Familial Frontotemporal Dementia (LEFFTDS) study, co-principal investigator of the North American Prodromal Synucleinopathy Consortium, and chair of the Coordinating Center for the Lewy Body Dementia Association's Research Centers of Excellence Program.

Dr. Boeve received his M.D. from the University of Florida. He further trained at Mayo Clinic School of Graduate Medical Education where he completed an internship in internal medicine, residency in neurology, and fellowships in both behavioral neurology and sleep medicine.

He received the Sleep Science Award from the American Academy of Neurology in 2018.

## Dr. Adam Boxer

Adam L. Boxer, M.D., Ph.D., is the Endowed Professor in Memory and Aging in the Department of Neurology at UCSF. He specializes in Alzheimer's disease, FTD, and atypical parkinsonism – in particular, CBS and PSP. His field of interest is clinical trials, and his research is focused on developing new treatments and biomarkers for neurodegenerative diseases, particularly those involving tau and TDP-43.

Dr. Boxer directs UCSF's Neurosciences Clinical Research Unit and the Alzheimer's Disease and Frontotemporal Degeneration Clinical Trials Program at the UCSF Memory and Aging Center (MAC) He also leads Four Repeat Tauopathy Neuroimaging Initiative (4RTNI), a multicenter, longitudinal tau PET and biomarker study focused on PSP and CBD. He is a co-chair with the FTD Treatment Study Group (FTSG), a program looking to speed up the development of new therapies for FTD.

He served as PI of the Advancing Research and Treatment for FTLD (ARTFL) Rare Disease Clinical Research Consortium, a collaborative project funded by the National Institutes of Health that included an 18-center North American research network to support the development of new therapies for FTLD. He has also been the PI for other multicenter, randomized, placebo controlled clinical trials in FTLD spectrum disorders, and has led a variety of clinical trials in FTD and PSP.

Dr. Boxer received his medical and doctorate degrees as part of the NIH-funded Medical Scientist Training Program at New York University Medical Center. He completed an internship in Internal Medicine at California Pacific Medical Center, a residency in Neurol-

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ogy at Stanford University Medical Center, and then a fellowship in behavioral neurology at UCSF.

He received the Edwin Boldrey Award from the San Francisco Neurological Society in 2002 for basic research in neurological disease, the 2005 John Douglas French Alzheimer's Foundation Alzheimer's Award, and a 2009 Hellman Family Foundation fellowship.

## Dr. Howie Rosen

Howie Rosen, M.D., is a professor of neurology at UCSF. He is the director of the Imaging Core at the MAC and oversees the California Alzheimer's Disease Center (CADC), both at UCSF. His responsibilities include training medical students, residents, and fellows; as well as evaluating new patients and managing care for existing ones.

A behavioral neurologist, Dr. Rosen's current research activities include serving as co-investigator for the Frontotemporal Dementia: Genes, Images, and Emotions study, which has been incorporated into ALLFTD. He also supervises unique programs that reach out to medically underserved communities in the Bay Area, in particular Chinese Americans. He seeks to overcome scientific and cultural barriers that impede the early and accurate diagnosis of neurodegenerative diseases in anticipation of when these diseases are treated before they can cause serious impacts on daily living.

His primary research interest is in the effects that atypical neurodegenerative diseases, such as FTD, have on the brain, especially the emotional systems. His current projects use psychophysiology and imaging to examine how these diseases affect self-awareness, and to determine how imaging and other biological markers can be used to track and to anticipate how these diseases affect the brain over time.

Recently, Dr. Rosen became director of Curriculum for Global Brain Health Institute (GBHI). He also serves as director of UCSF's Behavioral Neurology Training Program. Through these initiatives, he designs and supervises programs that prepare the next generation of dedicated professionals to carry on with this work until the threat posed by dementia is eradicated throughout the world.

He served as a PI for the LEFFTDS study, a collaborative project with the National Institute on Aging (NIA) and National Institute of Neurological Disorders and Stroke (NINDS) which focused on providing in-depth assessment of familial FTLD (f-FTLD) stemming from known genetic mutations at eight sites in North America.

Dr. Rosen, completed a combined BA/MD program at Boston University in 1989, a residency in Internal Medicine at Albert Einstein College of Medicine in the Bronx, New York, in 1992, and then a neurology residency at UCSF in 1996. After his residency, he pursued fellowship training in cognitive neuroscience and brain imaging at Washington University in St. Louis before returning to UCSF to join the faculty at the MAC in 1999.



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