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## Site Updates from CLARiTI & NACC: February 12, 2024

*The ADRC consortium for Clarity in ADRD Research Through Imaging*

### Welcome to CLARiTI

Dear colleagues,

CLARiTI was born out of our collective vision to acquire uniform imaging (SCAN) and fluid biomarkers in the ADRCs in such a way that it will be centrally integrated with the UDS, the ADRC standard blood collection protocol called ADCFB, and other affiliated ADRC data. These data will be accessible to the world through NACC. Just imagine the discoveries and advances that will be possible when we have large numbers of exquisite standardized molecular imaging paired with blood samples at NCRAD and eventual neuropathology. This thorough phenotyping effort on ADRC clinical core participants will result in new methods and markers for detecting some of the intersecting etiologies that cause cognitive impairment and provide temporal estimates of their asynchronous onset ages and disease durations. Our work together will also help bridge our field to newer more scalable biomarkers for accurate and comprehensive diagnoses, quickly validate novel biomarkers of currently unmeasurable common pathologies, and amplify the uses of existing methods to improve the lives of patients living with symptoms of one or more of the ADRDs or who may be in a preclinical phase.

We are working through the logistics of study start up! We would like to be enrolling participants by April. Let's see if we can do it. IRB approval is in-hand, many of the contracts are in place, and the administrative team is now scheduling conversations with each site to address your questions and understand your unique situation as you plan your startup of this project. In particular, we want to support your planning efforts to recruit diverse participants from your ADRC.

We now turn to establishing sub-awards with each site and NACC. Please be on the lookout for a survey from NACC that will form the basis of the structure of your subaward.

We will also cover this topic in the February 28<sup>th</sup> [webinar](#). There are many more details to cover. We will keep the communication flowing regularly through these email newsletters and we won't mind repeating things occasionally. Please check the [website](#) for links to materials and we will hopefully see you on our next webinar detailed below. And we are listening to you. The project is better because of your suggestions and feedback.

Thank you for being a part of this ADRC consortium!

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~~Sterling Johnson and Beth Mornino~~  
on behalf of the CLARiTI mPI team and investigators

## **CLARiTI Receives IRB Approval – Sites May Initiate Cede Application with Local IRB**

The CLARiTI protocol received IRB approval on January 19, 2024. Your site may now initiate a cede application with your local IRB to cede review to our single IRB, WCG. The approved documents, which include two consent templates (one for cognitively impaired, one for cognitively unimpaired), and the study protocol, are filed [here](#). Additional materials will be forthcoming.

## **Single IND has been submitted to the FDA**

Sterling Johnson, PhD, will hold a single IND for tracers NAV4694, MK-6240, and PI-2620 for CLARiTI. Sites using these tracers for CLARiTI will be monitored by the University of Wisconsin Clinical Research Office Central Monitoring System.

## **Updates on Radioligand Contracts**

Contracts are either in place or nearly complete with the companies who supply the several radioligands used in this study. The contract with Enigma/Meilleur is fully executed for amyloid tracer NAV4694; the contract with Lantheus/Cerveau is fully executed for tau tracer MK-6240. The contract for amyloid tracer florbetaben (FBB) with Life Molecular Imaging (LMI) is fully executed. The contract for tau tracer PI-2620 with LMI is very close. For sites who plan to manufacture flortaucipir (FTP), Lilly has confirmed that you will be able to continue to manufacture FTP for this project. We are close to a contract with Lilly for their commercially manufactured products. The support from these companies has been phenomenal!

## **ADRC Site Initiation Meetings**

CLARiTI is growing quickly in 2024. To date, we have held site initiation meetings with: 1Florida, Banner Health Arizona, Boston University, Cleveland Clinic Ohio, Duke/University of North Carolina at Chapel Hill, Mayo-Rochester, Massachusetts General Hospital, New York University, Rush University, Stanford, University of Alabama at Birmingham, University of California Davis, University of California San Diego, University of California San Francisco, University of Michigan, University of Pennsylvania, University of Pittsburgh, University of Texas San Antonio, University of Wisconsin, Vanderbilt, and Wake Forest University. Many more are scheduled.

During the initiation meeting, members of the CLARiTI team provide a study overview and site-readiness checklist. If we haven't been in touch with your site yet, we will in the coming weeks. Click here for the [site initiation slide deck](#).

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## **CLARiTI Webinars**

### **CLARiTI - NACC Flow & Subaward Setup**

Wednesday, February 28, 2024, at 12:00 pm – 1:00 pm CT (1:00 - 2:00 pm ET / 10:00 - 11:00 am PT)

Register today at [this zoom link](#) and please share with your teams.

### **CLARiTI - Recruiting for Inclusion**

Wednesday, March 27, 2024, at 1:30-2:30 CT ([2:30-3:30 pm ET / 11:30 am - 12:30 pm PT](#))

Please save the date, an invitation with zoom link will be shared soon.

### **Introducing CLARiTI: Informational Webinar**

Watch video now available from December 15, 2023: <https://naccdata.org/nacc-collaborations/clariti>

## **CLARiTI in the News**

Early this January, CLARiTI announced the study launch and saw great press pick up. Please feel free to use any links and media features in your own outreach work.

See more CLARiTI news features: <https://www.adrc.wisc.edu/news/claritistudyfunding>

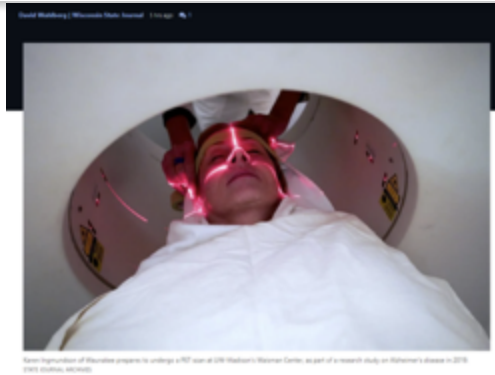
### **University of Washington plays key role in \$150M CLARiTI study for Alzheimer's and related dementias research**

The [National Alzheimer's Coordinating Center](#) (NACC) will receive nearly \$7 million of a new \$150 million grant to collaborate on a study called Clarity in Alzheimer's Disease and Related Dementias Research Through Imaging (CLARiTI). The five-year study funded by the National Institute on Aging will provide cutting-edge imaging and blood-based biomarker data for researchers worldwide to advance Alzheimer's and related dementias research. Read the full blog [here](#).

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### **CLARiTI Staff Visits Cyclotron**

CLARiTI’s Wisconsin administrative staff visited the [UW Cyclotron Lab](#) in January. The team learned the fascinating ins-and-outs of creating radionuclides for medical diagnosis.



### **Contact Us**

**CLARiTI: The ADRC Consortium for Clarity in ADRD Through Imaging**

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