

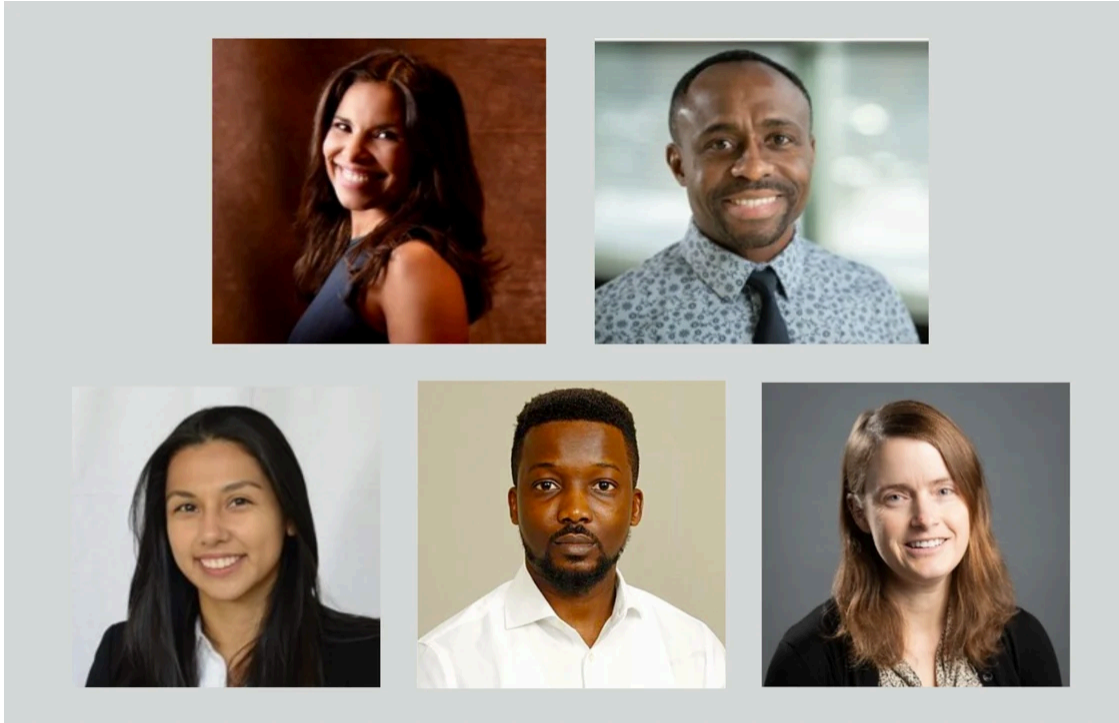


# CLARiTI CONNECT

**March 25, 2024**

*CLARiTI Connect is a newsletter distributed by the CLARiTI administrative teams at UW–Madison and the National Alzheimer's Coordinating Center. CLARiTI Connect contains current information about study progress, operations updates, news and training opportunities. Thank you for connecting!*

## **Meet the CLARiTI Inclusion Core**



**Top to bottom and left to right: Dr. Mónica Rivera-Mindt,  
Dr. Ozioma Okonkwo, Dr. Vanessa Guzman,  
Dr. Adeyinka Ajayi and Anne Buffington.  
Not pictured: Eva Schulte**

The CLARiTI Inclusion Core (IC) will draw on culturally informed, community-engaged research (CER) methods to promote the engagement, recruitment and retention of participants from historically under-represented groups. IC team members will provide training and consultation for your local ADRC staff on CER methods. The IC will also offer participant navigation services and convene a Community-Science Partnership Board (CSPB) to guide the work of the IC.

Dr. Ozioma Okonkwo and Dr. Mónica Rivera-Mindt co-lead the Core.

- Dr. Okonkwo is a Professor in the Department of Medicine at the University of Wisconsin School of Medicine and Public Health. His research focuses on clarifying how alterations in the brain and other biomolecules place some cognitively-normal individuals on a pernicious trajectory that culminates in symptomatic Alzheimer's disease. In this context, Dr. Okonkwo is also interested in discovering new knowledge concerning the modulation of the link between brain changes and cognitive decline by both modifiable and non-modifiable factors. Overlaid on this research agenda are investigations of health inequities, and how such inequities exacerbate or ameliorate the impact of biomarkers on clinical phenotypes. Dr Okonkwo is passionate about mentoring emerging leaders in the field, and co-directs the NIH-funded Health Equity Scholars Program.
- Dr. Mónica Rivera-Mindt is a Professor of Psychology, Latino/a/x/e Studies, and African & African American Studies at Fordham University. She holds a joint appointment in Neurology and Psychiatry at the Icahn School of Medicine at Mount Sinai (ISMMS). Dr. Rivera-Mindt is a bilingual (English/Spanish) community-based, brain health equity researcher primarily focused on cultural neuroscience, health inequities, and cognitive aging in Latinx, Black, and other culturally/linguistically diverse populations.

Dr. Adeyinka Ajayi, Anne Buffington, Dr. Vanessa Guzman, and Eva Schulte collaborate to provide IC services.

- Dr. Adeyinka (Yinka) Ajayi is a physician and global health professional with experience in health education, health inequities, and community research. He works with Dr. Rivera-Mindt at ISMMS as a Project Manager.
- Anne Buffington, MPH, recently joined the Okonkwo lab as a CLARiTI Program Manager and has extensive experience managing multi-site studies in the UW-Madison Department of Surgery.
- Dr. Vanessa Guzman is consulting on the Inclusion Core work. She is a bilingual/bi-cultural neuropsychologist and Assistant Professor-Research Track in the Department of Neurology at ISMMS. Dr. Guzman has over 25 years of experience working with underrepresented populations, including indigenous communities and immigrant families in both urban and rural settings.
- Eva Schulte recently joined the CLARiTI Inclusion Core as a Community Research Navigator. Eva has experience working with community organizations and underrepresented populations, including indigenous communities and immigrant families in both urban and rural settings. She has

worked as a Certified Healthcare Interpreter (English/Spanish), helping patients and families navigate complex medical situations.

Please reach out to [Dr. Adeyinka Ajayi](#) or [Anne Buffington](#) with any questions or suggestions for IC programming.

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## Inclusion Core Survey

The Inclusion Core sent a survey to all sites today, March 25, to help guide programming. The survey was sent to site investigators, ORE Core Leaders, and other key stakeholders at each site. Thank you for participating.

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## Inclusion Core Webinar

*Register now!*

# CLARiTI WEBINAR

## Study Startup & Inclusion Processes

Wednesday, March 27, 2024  
2:30 - 3:30pm ET



Join us Wednesday, March 27th at 2:30-3:30pm ET for the next CLARiTI Webinar to learn more about inclusion efforts and programming.

[Register for the Webinar](#)

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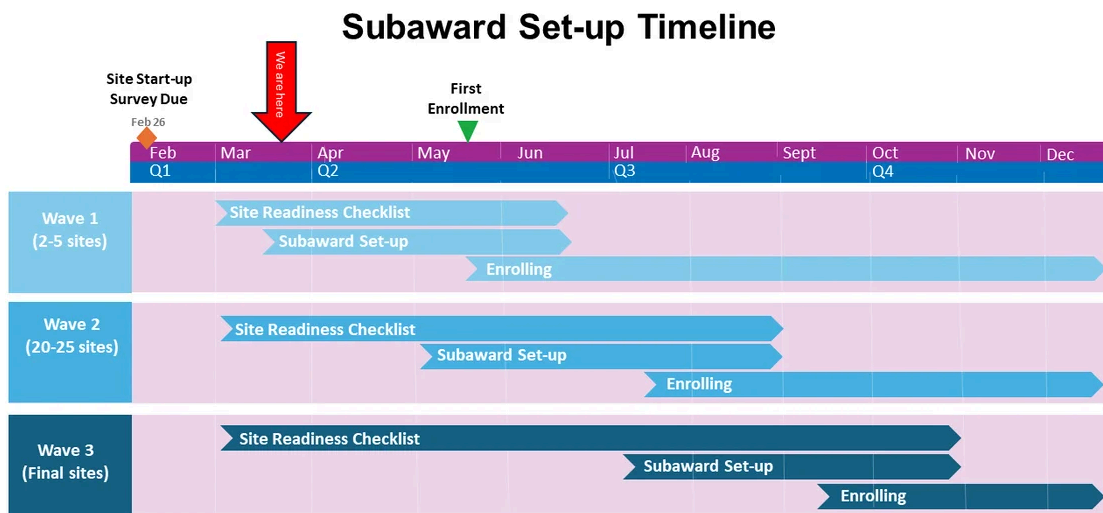
## Subaward Updates

NACC is finalizing all documentation for the subaward set-up process reviewed at February's webinar ([view slides and recording - see slide 21 for timeline pictured below](#)). The standard subaward template, scope of work, and tools to collect and track subaward set-up progress will be finalized soon. As a reminder, the next steps are as follows:

- Your CLARiTI project coordinator will distribute the Scope of Work to sites in the next few weeks.

- Next, sites will receive communication from NACC to begin collecting documentation to initiate the subaward process. These will be rolled out in three waves (see figure below). During this step, you will be asked to submit forms to NACC necessary to generate your draft subaward agreement.
- In parallel, the Wisconsin CLARiTI team will be evaluating the procedure costs submitted in the Site Start-up Survey and aligning with the overall study budget. They will reach out to the ADRC sites with any potential modifications. Once finalized, the CLARiTI team will forward budget documentation to the NACC team on the sites' behalf.

We look forward to collaborating with you on these exciting steps towards the first enrollment milestone.



## CLARiTI Pilot Sites

The Wisconsin and Stanford ADRCs will serve as pilots of our activation processes as they are the sites represented by administrative co-leads, Dr. Sterling Johnson and Dr. Beth Mormino. They will begin the process on March 25 and the next wave of sites will begin mid-April. Our hope is to ensure a smooth workflow before other sites begin the subaward process.



IND #170860, under Dr. Sterling Johnson, was approved by the FDA on March 6, 2024. This IND covers the following tracers that will be delivered to sites: MK-6240, NAV4694, and PI-2620. In the coming weeks, your CLARiTI project coordinator will reach out to confirm radioligand choices and confirm delivery address of tracers. If necessary, your site will be added to the relevant work orders with the radioligand companies, and your coordinator will collect a 1572 form from your site investigator. For sites that are producing tracers (PiB, NAV4694, FTP, PI-2620) or receiving delivery of non-FDA approved FTP, you will need to reference your local site IND.

Important documents such as the Study May Proceed letter and the 1572 form can be found in the Site Start-Up Documents Folder.

[Site Start-Up Documents Folder](#)

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## **CLARiTI is hiring!**

### **CLARiTI Regulatory Coordinator**

The UW Madison CLARiTI team is hiring! The incumbent will join the compliance team to support 37 external sites in study compliance and monitoring. Job duties include providing guidance to study site teams regarding protocol implementation, providing centralized monitoring of site regulatory compliance, reviewing the timeliness of data entry, and ensuring FDA IND compliance associated with PET imaging.

<https://jobs.wisc.edu/jobs/clariti-regulatory-coordinator-madison-wisconsin-united-states>

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## **Submissions for CLARiTI Connect**

Please share your CLARiTI related news, job postings, etc., with [Phoebe Frenette](#), [CLARiTI Communications Specialist](#).

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## **Contact Us:**

**Email:** [clariti@medicine.wisc.edu](mailto:clariti@medicine.wisc.edu)

**Web:** <https://naccddata.org/nacc-collaborations/clariti>



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