# CLARiTI CONNECT

**September 26, 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!*

## First Scan for CLARiTI Study: A Milestone for Health Equity in Alzheimer's Research

On August 22, 2024, the Wisconsin ADRC successfully completed its first scan in the CLARiTI study. As a pilot site, Wisconsin is proud to lead the charge to operationalize this nationwide study, marking an important step toward full implementation.

Our first participant is African American, a fulltime caregiver, and has been contributing to AD research since 2018. She is a true testament to the dedication of our study participants. This milestone underscores the study's commitment to advancing health equity. By focusing on diverse populations, CLARiTI aims to address disparities in Alzheimer's research and improve outcomes for all communities. We are excited to share this significant milestone and look forward to continuing to work with our ADRC partners to drive inclusive, innovative research forward.



CLARiTI's first participant, scanned at the Wisconsin ADRC, is thanked by Dr. Sterling Johnson, mPI. (Photo used with permission).

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## Study Start Up Updates

### Important CLARiTI Update: Protocol V3 Approval

On September 19, 2024, WCG IRB officially approved CLARiTI Protocol V3 and Consent Form Templates V3 and an email was sent out to all staff the same day with instructions for this change. These are now the official study documents. All previous versions of the protocol and consent forms are now obsolete and must be discontinued.

Please note the major changes below:
**Protocol V3** - changing the eligibility age to 50 and older for all participants.
**Consent Form Template V3** - we are removing the Disclosure consent form and moving forward with two consent template options. Use one or both as applicable for your participant population:

- CLARiTI Consent Template V3: Main consent template will describe all study procedures, but will not have any language about the opinion for return of results (RoR).
- CLARiTI Consent w/ RoR Template V3: This consent template will include the option for participants to receive their Amyloid and/or Tau PET results. Sites will still have the ability to edit the language to fit specific needs.

Review this document for a summary of protocol and consent changes, along w/ action items required. **You are required to send drafts of your updated consent forms to your project coordinator and CLARiTI regulatory team in advance of submitting to WCG.**

## CLARiTI Study Handbook Release

The CLARiTI Study Handbook V1 is now available. Sites should reference the handbook alongside the study protocol for guidance and compliance to properly conduct the study. The handbook outlines:

- Study Organization/Roles and Responsibilities
- Study Contacts
- Study Activation
- Study Case Report Forms
- Study Procedures
- Regulatory
- Data Submission
- Subawards from NACC
- Inclusion
- Return of Results

| CLARiTI Study Handbook |
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## CLARiTI Box Server Change

CLARiTI's online Box folder containing study documents has moved to a new and improved Box drive. The drive is named "(Public) CLARiTI Study Documents for ADRC Sites".



New links to folders and materials are now live on the CLARiTI website and in our Study Handbook. Thank you for adjusting to this new server, and please let us know if you are having any trouble finding materials. You may reach out to your CLARiTI project coordinator at any time.

Please bookmark this new server. The old server will be closed down to access on October 1.

| CLARiTI Study Documents for ADRC Sites |
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## Central Monitoring

Study monitoring for all CLARiTI sites will be provided by the University of Wisconsin Central Monitoring Service (CMS) and will be paid for by CLARiTI funding. Individual sites will not receive an invoice. Central monitoring is required for all sites participating in CLARiTI regardless of whether the site is referencing central IND #170860. It is the sponsor's responsibility to ensure full compliance of all sites participating in CLARiTI.

When your site has received WCG approval, CLARiTI will be reaching out to schedule a Site Initiation Visit (SIV), a mandatory meeting which includes a regulatory review of your e-binder and training on the protocol and the CRFs. **SIVs will be scheduled about a month in advance so that your team**, including Site PI, are able to block time for this important component of the study. These can be scheduled before receiving full execution of the subaward from NACC.

**Attendees required:** Site PI, program manager, study coordinator, outreach specialist, and regulatory contact should attend the protocol review. The same personnel should plan to attend other sections of the SIV relevant to their day to day work on CLARiTI. The overall SIV is approximately five hours in length. View the agenda below for required attendance.

**All regulatory documents must be completed before the SIV.** In addition to finalizing the subaward, the SIV is the last step prior to site activation. CLARiTI's regulatory team will be present at CLARiTI office hours if you have questions you would like to ask them in preparation for your SIV.

For questions please contact your CLARiTI project coordinator or regulatory team.

**View SIV Agenda**

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**Update on Subawards**

Last week NACC emailed site contacts with an **important update regarding the CLARiTI subaward process.** Following the receipt of the CLARiTI Year 2 Notice of Award (NoA), the CLARiTI leadership team will create your subaward from the year 2 grant period, which will have the budget period of 9/1/2024 - 8/31/2025 (and usual pre-award spending authority of 90 days, enabling billing to begin 6/1/2024.

The email containing details of the update was sent to ADRC Administrators, Subaward contacts, Site PIs, ORE Core leadership, and Project Managers on Thursday, September 12, 2024.

ADRCs will be receiving site-specific communications from NACC regarding status of their subawards over the course of the next few weeks.

Please email Phoebe at pfrenette@medicine.wisc.edu if you need a copy of that email sent again or need to add a contact to our distribution list.

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**CLARiTI Study Start-Up Dashboard**

Be sure to bookmark and regularly check the CLARiTI "Study Start-Up" dashboard to track your site's progress completing study start-up requirements. The dashboard shows progress of all sites based on the status of their site readiness checklist tasks. Your CLARiTI Project Coordinator can help identify any outstanding tasks and answer questions. Our team is eager to assist and support each site during the implementation of the study to ensure the success of CLARiTI.

**View Your Site's Status**

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**"Disclosure Core" is Renamed to "Return of Results Core"**

The Disclosure Core has decided to change the name of their core to "Return of Results" Core or RoR. This mirrors a shift within the field of moving away from the term 'disclosure' when referring to the return of research results. The connotation of disclosure implies a release or revealing of information rather than returning participants' personal data to them. This name change is intended to reflect CLARiTI's dedication to collaboration, transparency and promoting autonomy for its participants.

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**Webinars & Events**



CLARiTI Webinar: Advanced MRI Sequences, Rationale, Goals and Procedures

**Monday, September 30 at 2:30 pm ET | 1:30 pm CT | 11:30 am PT**

Join us for this hour-long webinar where we will give a brief update about the CLARiTI study followed by an overview of CLARiTI's plans for Advanced MRI sequences, rationale, goals, and procedures, led by Dr. John Detre, Advanced MRI Lead and Co-Investigator. We will wrap up this webinar with an open Q&A session.

**Register today!**

CLARiTI Webinar: Visual Reads & PET Scan Processes

**August 28, 2024**

Review the webinar recording for brief updates about CLARiTI, followed by an overview from our Visual Reads Core about the PET scan processes for the study, with Dr. Gil Rabinovici, CLARiTI mPI, and the Visual Reads Core team.

### CLARiTI at the 2024 Hybrid Fall ADRC Meeting in Boston

We look forward to connecting with our ADRC colleagues at the upcoming Fall ADRC Meeting in Boston. CLARiTI will be presenting a session on Thursday, October 17th from 4:00 - 5:00pm ET. In addition to study updates, members of our Administrative Core and Inclusion Core will be presenting on the scientific and infrastructure impact of CLARiTI. A recording of the presentation will also be available after the Meeting.

Register for the Fall Meeting

### Office Hours

Join the CLARiTI Central Administration Team (CAT) and NACC to ask any questions you have about study start up. We hope that you will stop by to talk shop!

Friday, October 11 at 1:30 - 2:30pm CT - Add to Calendar

Office hours will be held in the CLARiTI meeting room on Zoom at https://uwmadison.zoom.us/my/clariti. Registration is not required.

*Staying the whole hour is not necessary and you can join anytime. Feel free to get your questions answered and hop off the call.

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### Advancing Brain Imaging with CLARiTI - Interview with Dr. Gil Rabinovici

*The CLARiTI team sat down with Dr. Gil Rabinovici, leader of the CLARiTI Visual Reads Core Team, to discuss the plans and what excites him about CLARiTI. Read an excerpt below and click on the link for the full interview.*

**Interviewer:** Please tell us about plans for CLARiTI's Visual Reads Core Team.

*Dr. Gil Rabinovici, CLARiTI mPI and Visual Reads Core Lead*

**Dr. Rabinovici:** In the spirit of CLARiTI, which is a multi-site collaboration across the ADRCs, we put together a team of established MD clinicians with expertise in reading Amyloid and Tau PET scans. The multidisciplinary team includes neurologists, radiologists, and nuclear medicine experts across the ADRCs. CLARiTI images will be assigned to our different readers.

We have a system in place where the reader does a visual interpretation of the scan using established criteria and assigns a quantification - a number associated with the PET uptake of Amyloid or Tau. The number indicates if the reads are at an elevated or non-elevated level for Amyloid and Tau. The outcome of the visual read will be returned to the sites for your local use and may be used for disclosing the result to your participants.

Read the full interview

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### Meet the CLARiTI Team

**Jingyan "Jane" Xia, NACC Grants & Finance Manager**

Jingyan "Jane" Xia is the Grants & Finance Manager at NACC. Jane works with the CLARiTI Teams at NACC and Wisconsin to provide the overall support and management of the NACC CLARiTI post awards, especially the subawards.

Jane has been working at UW for about 3 years. Prior to that, she worked for the University of Missouri for the Pre- and Post-awards for 15 years.

Outside of work, Jane likes to walk on local trails, tour national parks, and cook for her family.

**Emily Almeda, NACC Administrative Coordinator**



Emily Almeda is an Administrative Coordinator at NACC, where she plays a key role in supporting the Grants & Finance team through dissemination of subaward surveys, administration of subawards, and processing invoices.

Prior to joining NACC, Emily gained valuable experience working at a private equity firm specializing in multi-family real estate investments.

Her transition to NACC has been fulfilling, as she enjoys being part of a team dedicated to Alzheimer's research. Outside of work, Emily enjoys spending time with her friends and family, experimenting with new recipes in the kitchen, and staying active.

**Haley Kohl, Return of Results Core Coordinator**

Haley Kohl graduated from Eastern Michigan University in 2021 with a Bachelor of Science in Psychology with a minor in Sociology. In 2022, she accepted a position at the Michigan Alzheimer's Disease Research Center (MADRC) as the Feedback team Research Assistant during the first year of the neuropsychological feedback pilot program roll out.



Following her time at the MADRC, she joined the Research Program on Cognition and Neuromodulation Based Interventions (RP-CNBI) in Dr. Annalise Rahman-Filipiak's lab in April 2023. There she acts as the lab coordinator for Dr. Rahman-Filipiak's Alzheimer's Disease Biomarker Return of results studies. For CLARiTI, Haley is the Return of Results Core Coordinator where she aids the Core leads with the creation and implementation of the CLARiTI Return of Results Toolkit.

**Stephen Cubbellotti, Data Scientist**

Dr. Stephen Cubbellotti is the Data Scientist for the Monica Rivera Mindt's Lab at Mount Sinai School of Medicine and a supporting Data Scientist for the CLARiTI project. He graduated with his PhD in Psychometrics from Fordham University. Stephen has served as a psychometrician with the American Board of Internal Medicine for 5 years and as a Data Analyst for 5 years at various companies including TeePublic, SeatGeek and FreshDirect.

When he is not "nerding out" about data, statistics, and programming, you can find him with his family or friends nerding out about board games, theatre, and music.

**Emily Weiler, Community Research Navigator**

Emily Weiler is based at Mount Sinai and is a community engagement professional with experience in patient recruitment, community partnerships, and program management. She holds an MSW from Fordham University and a BA in Public Health from American University. She was previously the Community Engagement Associate for the All of Us Research Program at Columbia University Irving Medical Center.



As a Community Research Navigator for CLARiTI, she will work closely with CRLs and assist PIs and PMs to develop inclusive recruitment strategies for centers. In her spare time, she enjoys biking in Prospect Park in Brooklyn.

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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:

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