August 7, 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!

**Important Study Operations Memo**

**CLARiTI MRI Sequences Memo**

CLARiTI's Advanced MRI Core has released a new memo that provides direction for the required and optional study MRI sequences. **Study teams are encouraged to review the memo immediately and begin plans for incorporating these sequences into your site's MRI protocols.**

[CLARiTI Operations Memos](#)

**CLARiTI Requires MRI Site Certification**

The CLARiTI Study will require a CLARiTI specific MRI Site/Scanner qualification prior to any participants being scanned. This includes sites that have previously completed SCAN, ADNI, or qualification for similar studies. CLARiTI MRI site qualifications involve importing the CLARiTI specific MRI sequences (provided by the Mayo Clinic's ADIR Lab), scanning an MRI phantom with the imported sequences, and uploading the certification scans to the CLARiTI project on LONI. Detailed instructions and scanner specific electronic protocol MRI files will be emailed to each site as part of study start up. CLARiTI MRI questions can be directed here: claritimri@mayo.edu.

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**CLARiTI Study Start-Up Dashboard**

CLARiTI has launched the "Study Start-Up" dashboard for sites to track progress as they move through study start-up activities. The dashboard shows progress of all...
To see how your site can complete outstanding tasks on the CLARiTI Study Start-Up dashboard, please view the checklist in our public Box folder: CLARiTI Site Readiness Checklist. This checklist will help you understand what needs to be done to prepare your site for the study. As you complete each item on the checklist, inform your site's project coordinator, Kelsey Shuda or Hanzhe Gao, so they can update the dashboard's task status.

Your 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. We look forward to working together closely to ensure the success of CLARiTI.

Central Monitoring

Update: Study monitoring for CLARiTI 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 if the site is referencing IND #170860 under Dr. Sterling Johnson. It is the sponsor's responsibility to ensure full compliance of all sites participating in CLARiTI.

Subaward Updates

The subawards process has been initiated! All sites participating in Year 1 should have received an email notification from NACC sent to the Grant Administrator, Site PI, Study Coordinator, and ADRC Administrator that included the Scope of Work, Budget & Payment Terms, and instructions to provide documentation via a REDCap survey.

Once all documentation is received and the subaward is drafted, we anticipate a 6-to 10-week process to draft and fully execute the CLARiTI subaward agreement. We
look forward to supporting you through the subaward process.

Any questions related to the Scope of Work or Budget and Payment Terms can be directed to clariti@medicine.wisc.edu. Any questions related to documentation or subaward processes can be directed to naccgrants@uw.edu.

**Study Protocol V2 & Consent Forms V2**

As a reminder, please always use the most current regulatory documents. The current regulatory document versions include:

- CLARiTI Study Protocol V2
- CLARiTI Template Consent Form - Cognitively Unimpaired V2
- CLARiTI Template Consent Form - Cognitively Impaired V2
- CLARiTI Template Consent Form - Results Disclosure V1

**Events & Webinars**

CLARiTI Webinar: Visual Reads & PET Scan Processes

*Wednesday, August 28 at 1:00 pm ET | 12:00 pm CT | 10:00 am PT*

Join us for this hour-long webinar where we will give a brief update about the CLARiTI Program, followed by an overview from our Visual Reads Core about the PET scan processes for the study, with Dr. Gil Rabinovici, CLARiTI mPI and Visual Reads Core Lead. We will wrap up this webinar with an open Q&A session. This webinar is hosted by NACC in support of the CLARiTI project.

Register today!
CLARiTI Webinar: NCRAD / Blood Biomarkers in CLARiTI & Neuropath Overview

June 20, 2024

Review the recording of this hour-long webinar for brief updates about CLARiTI, followed by a presentation on Blood Biomarkers / NCRAD protocols and a Neuropath overview, led by CLARiTI Plasma Biomarker Core co-leads, Dr. Tatiana Foroud and Dr. Jeff Dage, and Neuropathology Core lead Dr. Dirk Keene.

Watch the Recording

Study Start-Up Office Hours

Join the CLARiTI Central Administration Team (CAT) and NACC to ask any questions you have about study start up. Our project coordinators, regulatory specialists, project managers, neuroimaging and communications team will be on the call to help talk through study start up at your site. It will be informal and not recorded, we hope that you will stop by to talk shop! Office hours will be held in the CLARiTI meeting room on Zoom at https://uwmadison.zoom.us/my/clariti. Registration is not required.

- Thursday, August 29 at 10:00 - 11:00am CT - Add to Calendar
- Tuesday, September 10 at 2:00 - 3:00pm CT - Add to Calendar
- Wednesday, September 18 at 10:00 - 11:00am CT - Add to Calendar
- Friday, October 11 at 1:30 - 2:30pm CT - Add to Calendar
Inclusion Corner

Community-Science Partnership Board

The Inclusion Core would like to thank our ADRC partners, especially the ORE Cores, for their nominations for the Inclusion Core's Community-Science Partnership Board. The nominees reflected an impressive breadth of experiences and personal backgrounds that will be invaluable as we engage underrepresented populations.

We are reviewing nominations now and will finalize and convene the CSP Board later this summer. While the deadline to submit nominations has passed, we always welcome the opportunity to connect with new community voices and, therefore, will consider additional nominees on a rolling basis throughout CLARiTI's lifespan.

Our work can only be made better by the valuable feedback of our community members and inclusion experts. For any questions or comments, please reach out to us at clariti-inclusion@medicine.wisc.edu.

Meet the CLARiTI Team

Heather O'Connell, CLARiTI Program Manager at NACC

Heather is NACC's CLARiTI Program Manager, spearheading the implementation of NACC's scope of work, which includes establishing CLARiTI's technical infrastructure, administering subawards, facilitating communication dissemination, and contributing research expertise. To her role, she brings extensive experience in clinical study management, data management, and product management from the medical device industry.
Outside of work, Heather enjoys golf, gym/fitness, jogging, broomball, kids' playdates, lake time, upcycling leftovers, and hosting family gatherings. She and her partner, Rob, have a 4-year-old daughter named Coralaine.

Heather is passionate about brain health and advancing AD research.

Brittany Sloan, Senior Regulatory Coordinator, Admin Core at UW-Madison

The CLARiTI National Team at UW-Madison is pleased to introduce Brittany Sloan as our Senior Regulatory Coordinator. Brittany previously worked as the Regulatory Lead for ADNI and LEADS studies at the Alzheimer's Therapeutic Research Institute (ATRI) at the University of Southern California. Brittany also supported breast, prostate, and lung cancer research at the University of North Carolina, Chapel Hill (UNC) and Duke University.

Brittany loves contributing to innovative ways involving all people into meaningful clinical research. In her free time, she enjoys being outside and discovering hikes
with waterfalls. This fall she plans to explore hikes around the Pacific Northwest.

**Mabel Duran Rojas, Regulatory Coordinator, Admin Core at UW-Madison**

Mabel joins the CLARiTI team as a Regulatory Coordinator. Her educational background includes a bachelor's degree in nursing, a specialization in public health management, and a master's degree in clinical trials monitoring. Mabel worked for the last eight years in the pharmacovigilance area for the pharmaceutical industry.

She is passionate about sports, dancing, reading, movies, and culinary experiences; and her favorite time of year is summer, and her dream travel destination is Egypt. Outside of work, Mabel enjoys traveling, seeing landscapes, and building memories with her family.

**Carol Soppe, Clinical Research Supervisor, Visual Read Core at UCSF**

Carol Soppe is the PET Program Clinical Research Supervisor working directly with the Rabinovici Lab. She manages the operations associated with the CLARiTI Image Read Team and Visual Reads Core. Besides project management expertise, Carol brings over 20 years of research experience spanning fields from basic immunology, metabolic diseases and oncology to transplantation and autoimmunity.
Prior to joining the Memory and Aging Center in May 2024, she was an Associate Director of Research Operations at the UCSF Immune Tolerance Network. She has a professional science master's degree in biotechnology, MBT. In her spare time, Carol enjoys hiking, being mindful, practicing stoicism, brushing up on her Korean language skills, and listening to podcasts. She is a lapsed runner who has at least one more marathon in her that she plans to run in 2027.

**Terry Ward, Neuroimaging Analyst, Admin Core at UW-Madison**

Terry Ward joins the National Administrative team at UW-Madison. Terry's experience encompasses creating commercial medical device software for radiation treatment planning, integrating clinical applications on the CT scanner console, and the development of PET/CT devices at Philips.

Terry also has expertise in integrating MRI into treatment planning and focusing on auto-generation of treatment plans using exclusively MR data. Terry also provided neuro image analysis working with FDG PET and FMRI at the UW lab for Affective Neuroscience. In his free time, Terry enjoys frisbee golf and biking.

**Submissions for CLARiTI Connect**

Please share your CLARiTI related news, job postings, etc., with Phoebe Frenette, CLARiTI Communications Specialist.

**Contact Us:**

Email: clariti@medicine.wisc.edu
Web: https://naccdata.org/nacc-collaborations/clariti