Date: 10-26-2026

IRB #: 2026-0044-Lehman
Title: Investigating Changes in Numerical and Mathematical Processing in individuals with CBD and lvPPA
Creation Date: 1-21-2026
End Date: 2-1-2027
Status: Approved
Principal Investigator: Silvia Hargrove
Review Board: Exempt, Expedited & Limited IRB
Sponsor: CUNY - Graduate Center

Study History

Submission Type Legacy	Review Type Unassigned	Decision
Submission Type Modification	Review Type Limited	Decision Exempt - Limited IRB
Submission Type Modification	Review Type Limited	Decision Exempt - Limited IRB

Key Study Contacts

Member Mira Goral(10861340)	Role Co-Principal Investigator	Contact mira.goral40@login.cuny.edu
Member Silvia Hargrove	Role Principal Investigator	Contact silvia.hargrove56@login.cuny.edu
Member Silvia Hargrove	Role Primary Contact	Contact silvia.hargrove56@login.cuny.edu

Legacy Submission

Study Status Legacy Submission

*required

Legacy Submission Requirement for Projects Migrated from IRBManager.

For projects that were reviewed and approved by the HRPP/IRB in IRBManager, a Legacy Submission in Cayuse Human Ethics (HE) must be submitted before any changes can be requested via a Modification submission. The Legacy Submission will not be routed for HRPP/IRB review, but is instead the process for entering information from the most recent approved IRBManager application into the Cayuse HE record.

After a Legacy Submission is submitted, Modifications can be submitted to request changes. Depending on the changes requested in a Modification, it may or may not be necessary for the research team to complete a full Cayuse HE IRB application. Some simple changes will not require completing the full application.

Please make a selection below to indicate if this is the Legacy Submission (a one-time submission) or a subsequent submission to request a Modification.

HRPP Staff Only: Full Legacy Submission

✓ **HRPP Staff Only:** IRBManager PDF Package only

Research Team: Modification

Research Team: Administrative Modification (limited submission)

Administrative Modification should only be selected if you are making any of the following changes.

- Minor changes to approved recruitment materials, consent forms or other documents
- Submission of translated materials, site approvals, ancillary approvals, or other similar documents
- Changes to project personnel (**not** including changes to Principal Investigator or Faculty Advisor)

For all other changes, select **Research Team: Modification**

CUNY Project Personnel

CUNY Researchers

Please identify the CUNY Principal Investigator and all CUNY personnel who will be involved in carrying out the research. For the purposes of CUNY HRPP/IRB, a researcher is any individual who i) serves as the Principal Investigator (PI) or co-investigator; ii) interacts directly with the research subjects for research purposes; or iii) has access to identifiable private information about the human subjects for research purposes. HRPP-112: Researcher Responsibilities

Note: Only CUNY affiliated personnel should be identified or listed here.

*required

Principal Investigator (PI)

The PI must have a current affiliation at CUNY. For guidance on who can serve as PI, please see HRPP-113: CUNY HRPP Policy: Principal Investigator Qualifications & Responsibilities

Name: Silvia Hargrove
Organization: Users loaded with unmatched Organization affiliation.
Address:
Phone:
Email: silvia.hargrove56@login.cuny.edu

Faculty Advisor

If the PI is a Graduate Student or a Postdoctoral Scholar, provide the name of the Faculty Advisor. The person listed as the Faculty Advisor will have edit access to this study, can create submissions after Initial approval, and will be included in study communications.

- *HRPP-114: Faculty Advisor or Research Program Director Responsibilities*

Name: Mira Goral(10861340)
Organization: Lehman College - Speech-Language-Hearing Sci
Address: 250 Bedford Park Blvd West , Bronx, NY 10468-1527
Phone:
Email: mira.goral40@login.cuny.edu

Investigator(s)

All research personnel listed as Investigators will have edit access to this study, can create submissions after Initial approval, and will be included in study communications.

*required

Primary Contact

The PI is automatically a Primary Contact. Any other people listed as a Primary Contact will have edit access to this study, can create submissions after Initial approval, and will be included in study communications.

Name: Silvia Hargrove
Organization: Users loaded with unmatched Organization affiliation.
Address:
Phone:
Email: silvia.hargrove56@login.cuny.edu

Other CUNY Research Personnel

Any people listed as Other CUNY Research Personnel will not be able to access the study, but should be listed here to confirm training completion.

Legacy Attachment(s)

*required

Please attach a pdf of the most recent approved IRBManager package.

Protocol Form-2026-08-17-13-18.pdf

Modification Submission

Modification Information

Any change to the previously approved application must be submitted through a Modification and receive approval prior to implementing the requested change.

The **only** way to make a change to a Human Ethics application is through a Modification submission.

If you do not intend to make changes to the study, please delete this Modification: clicking on Submission Details near the top left, then click on the grey button with a trash can to delete this submission.

- To report an event or incident with the study, an Incident submission may be needed. HRPP-501: Event Reporting and Review
- To renew study approval, submit a Renewal.
- If the study is complete, a Closure submission may be needed. HRPP-108: Project Continuation and Closure

*required

Modification Summary

Please briefly summarize the changes you are requesting in this Modification.

We would like to update the recruitment materials, in particular the flyers and website advertisement.

*required

Justification

Please provide the reasons for the proposed changes.

The wording in the previous version of the flyers was a bit cumbersome and convoluted and we wanted to simplify the wording to make it more accessible.

Study Status Legacy Submission

*required

Legacy Submission Requirement for Projects Migrated from IRBManager.

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HRPP Staff Only: Full Legacy Submission

HRPP Staff Only: IRBManager PDF Package only

Research Team: Modification

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- Minor changes to approved recruitment materials, consent forms or other documents
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- Changes to project personnel (**not** including changes to Principal Investigator or Faculty Advisor)

For all other changes, select **Research Team: Modification**

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*required

Please indicate the Administrative Modification change(s).

Change to Personnel or Independent Researcher (NOT change to PI or Faculty Advisor)

Minor changes to an approved consent or assent form

✓ Minor changes to approved recruitment materials

Submission of translated versions of approved materials

Other ancillary documents (Institutional/Government permissions, Data Use Agreements, External IRB approvals, etc.)

*required

Study Status

Select the current status of the study

No subjects enrolled: No subjects have been enrolled

✓ **Ongoing enrollment:** Subject enrollment will occur going forward

No new enrollment; ongoing interactions: No new subjects will be enrolled, but interventions or interactions with already enrolled subjects will occur going forward

Data analysis only: No new subjects will be enrolled and no interactions with subjects will occur, but analysis of identifiable information will occur going forward

No analysis of identifiable information or any other human subjects research activities will occur going forward

CUNY Project Personnel

CUNY Researchers

Please identify the CUNY Principal Investigator and all CUNY personnel who will be involved in carrying out the research. For the purposes of CUNY HRPP/IRB, a researcher is any individual who i) serves as the Principal Investigator (PI) or co-investigator; ii) interacts directly with the research subjects for research purposes; or iii) has access to identifiable private information about the human subjects for research purposes. HRPP-112: Researcher Responsibilities

Note: Only CUNY affiliated personnel should be identified or listed here.

*required

Principal Investigator (PI)

The PI must have a current affiliation at CUNY. For guidance on who can serve as PI, please see HRPP-113: CUNY HRPP Policy: Principal Investigator Qualifications & Responsibilities

Name: Silvia Hargrove
Organization: Users loaded with unmatched Organization affiliation.
Address:
Phone:
Email: silvia.hargrove56@login.cuny.edu

*required

What is the Principal Investigator (PI)'s current affiliation with CUNY?

If you cannot find a person in the people finder, please contact CUNY_era@cuny.edu.

- *Graduate Students and Postdoctoral Scholars can serve as PI but must identify a Faculty Sponsor.*
- *Undergraduate Students cannot serve as PI. If this is an undergraduate student project, the PI must be a Full Time Faculty member.*
- *A CUNY affiliate conducting research research on behalf of another institution (for example, a staff member who is a student at another school and wants to recruit participants at CUNY) should seek guidance from their HRPP coordinator.*

Full Time Faculty

✓ Graduate Student

Postdoctoral Scholar

Adjunct Faculty

Full Time Staff

Other

This is an Undergraduate Student's project, led by a Full Time Faculty member as PI.

*required

Faculty Advisor

If the PI is a Graduate Student or a Postdoctoral Scholar, provide the name of the Faculty Advisor. The person listed as the Faculty Advisor will have edit access to this study, can create submissions after Initial approval, and will be included in study communications.

- *HRPP-114: Faculty Advisor or Research Program Director Responsibilities*

Name: Mira Goral(10861340)
Organization: Lehman College - Speech-Language-Hearing Sci
Address: 250 Bedford Park Blvd West , Bronx, NY 10468-1527
Phone:
Email: mira.goral40@login.cuny.edu

Investigator(s)

All research personnel listed as Investigators will have edit access to this study, can create submissions after Initial approval, and will be included in study communications.

*required

Primary Contact

The PI is automatically a Primary Contact. Any other people listed as a Primary Contact will have edit access to this study, can create submissions after Initial approval, and will be included in study communications.
Name: Silvia Hargrove
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Email: silvia.hargrove56@login.cuny.edu

Other CUNY Research Personnel

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*required

Are there any CUNY personnel who will be involved in the study whose name you cannot find using the Find People search function?

- Yes
- ✓ No

*required

Independent Researchers

An Independent Researcher is someone who is not affiliated with CUNY (i.e., not a current CUNY student, faculty, or staff member) and not affiliated with or acting on behalf of a collaborating institution, who will conduct research activities. Non-affiliated study personnel who ARE acting on behalf of another institution are not "independent researchers" and should not be listed here. These personnel will require either an IRB approval from their institution or an IRB Authorization Agreement.

Will any Independent Researchers be involved as study personnel?

- Yes
- ✓ No

Conflict of Interest

*required

Financial Conflict of Interest

Do any CUNY project personnel have a financial conflict of interest (FCOI) as determined by the CUNY Conflicts Committee?

Yes

✓ No

Other Potential Conflicts of Interest or Commitment

Do any CUNY project personnel have any non-financial relationships or commitments that could affect the design, conduct, reporting, or review of this research?

Yes

✓ No

Legacy Attachment(s)

Please attach a pdf of the most recent approved IRBManager package.

Protocol Form-2026-08-17-13-18.pdf

*required

Recruitment Documents

Flyer (healthy).pdf

Flyer (patients).pdf

Advertisement - website.docx

Modification Submission

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*required

Modification Summary

Please briefly summarize the changes you are requesting in this Modification.

We would like to request a modification of the current approved study protocol to allow remote administration of testing sessions via Zoom. Participants would be able to complete the assessments from their homes without traveling to the designated testing location. This modification is intended to improve accessibility, reduce travel demands and participant burden.

*required

Justification

Please provide the reasons for the proposed changes.

Recruitment has been limited by the requirement for in-person testing, as many potential participants are unable to travel to the testing location. In addition, several currently enrolled participants have relocated, making in-person participation difficult, time-consuming, and expensive. Allowing remote testing would reduce these barriers, broaden access to the study, and support participant retention and completion of the longitudinal assessments.

Study Status Legacy Submission

*required

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HRPP Staff Only: IRBManager PDF Package only

✓ **Research Team**: Modification

Research Team: Administrative Modification (limited submission)

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---

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Getting Started

About Cayuse Human Ethics

Cayuse Human Ethics is an interactive smart form with branching logic. As you answer questions, new sections will appear on the left-hand side. You do not have to finish the application in one sitting. All information can be saved.

- Throughout the form, click the question mark icon that appears in the top right corner of each section for guidance and definitions.
- For details on tracking your submission status and completing Cayuse Human Ethics Tasks, use the in-app Help (the blue question mark near the bottom right).
- For help with HRPP policies, IRB requirements, and navigating Cayuse Human Ethics, contact your HRPP Coordinator or visit the CUNY Office of Research website.

*required

I have read the information above, will consult all relevant CUNY policies and obtain guidance as I proceed, and I am ready to begin this submission.

✓ Yes

CUNY Project Personnel

CUNY Researchers

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Address:
Phone:
Email: silvia.hargrove56@login.cuny.edu

*required

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Full Time Faculty

✓ Graduate Student

Postdoctoral Scholar

Adjunct Faculty

Full Time Staff

Other

This is an Undergraduate Student's project, led by a Full Time Faculty member as PI.

*required

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Other CUNY Research Personnel

Any people listed as Other CUNY Research Personnel will not be able to access the study, but should be listed here to confirm training completion.

*required

Are there any CUNY personnel who will be involved in the study whose name you cannot find using the Find People search function?

- Yes
- ✓ No

*required

Independent Researchers

An Independent Researcher is someone who is not affiliated with CUNY (i.e., not a current CUNY student, faculty, or staff member) and not affiliated with or acting on behalf of a collaborating institution, who will conduct research activities. Non-affiliated study personnel who ARE acting on behalf of another institution are not "independent researchers" and should not be listed here. These personnel will require either an IRB approval from their institution or an IRB Authorization Agreement.

Will any Independent Researchers be involved as study personnel?

- Yes
- ✓ No

Conflict of Interest

*required

Financial Conflict of Interest

Do any CUNY project personnel have a financial conflict of interest (FCOI) as determined by the CUNY Conflicts Committee?

Yes

✓ No

*required

Other Potential Conflicts of Interest or Commitment

Do any CUNY project personnel have any non-financial relationships or commitments that could affect the design, conduct, reporting, or review of this research?

Yes

✓ No

Basic Information

*required

Project Type

Please select the type of project.

✓ Human Subjects Research Study

Project that does not involve human subjects research activities in which CUNY is engaged

118 Determination/Proposal Lacking Definite Plans for Involvement of Human Subjects

External Collaborators and IRB Oversight Arrangements

*required

Will this project involve collaboration with any non-CUNY External Sites/Institutions in the US?

Yes

✓ No

*required

International Activities

Will any research activities (recruitment, informed consent, data collection, etc.) occur and/or will the research team collect data from international locations and/or at non-US sites or institutions?

Yes

✓ No

*required

Research Type

What type of research will be conducted? Please select all that apply.

✓ Collection of data and/or biospecimens through **interactions and/or interventions** (e.g. surveys, interviews, blood draws, observation, physical tests, etc.)

Secondary analysis of data or biospecimens
(e.g., retrospective data review; use of existing data/biospecimens that were previously collected or that were generated for some purpose other than this research.)

Clinical Trial or Clinical Investigation

*required

Funding

Has funding for this project been requested or received? This includes external funding as well as internal funding or support.

✓ Yes

*required

Use the Sponsor Finder to select the source(s) of funding.

CUNY - Graduate Center

If you do not find the funder using the Sponsor Finder, please name them here.

Doctoral Student Research Grant (DSRG)

Funding or Grant Number

A funding number (or grant number) is a unique identifier assigned to a specific grant or award. If funding is internal (i.e., departmental/school funding), please indicate N/A.

DSRG (Round 21)

Cayuse SP Record Number

Please enter the Cayuse SP Record Number associated with this project.

2026-0044-Lehman

*required

Is funding pending or received?

Pending

✓ Received

*required

Attach the proposal and any award documents

Fw: DSRG: Congrats!.pdf

*required

Has funding for this project been requested or received by any of the following federal sponsors?

Department of Defense (DOD)

Department of Justice (DOJ)

National Institutes of Health (NIH)

✓ None of these apply

No

Study Design & Procedures

Research Design

*required

Background, Purpose, and Aims of the Study

Briefly describe the background, purpose, and aims of the research. Explain how the study contributes to existing knowledge.

Define acronyms the first time they are used and use consistent terminology.

The primary aim of this study is to investigate the progression of mathematical impairments in two neurodegenerative populations: individuals affected by corticobasal degeneration (CBD) and its subtypes (i.e., progressive supra nuclear palsy syndrome, Frontal behavioral spatial syndrome, corticobasal degeneration) and those with logopenic variant of primary progressive aphasia (lvPPA). These conditions are expected to affect numerical and language-based abilities in different ways. A group of neurologically healthy individuals will also be included as a control group and will complete the same study procedures across the same testing intervals. With this study, we aim to establish a connection between the three representational codes proposed in the Triple Code Model (Deheane et al., 1995, 2003) - the analog magnitude code, the verbal word frame, and the visual Arabic word form - and the anatomical correlates that characterize the two pathologies.

*required

Research Objectives, Questions, and Hypotheses

Provide the research objectives, questions, and hypothesis(es). For qualitative or exploratory research, describe any working hypothesis or what you expect to find.

Research questions:

1. What is the trajectory of decline in everyday numerical skills over time in CBD and lvPPA? Specifically, do the NADL scores change across three time points (baseline, 3 months, and 6 months), and does the rate or pattern of decline differ between the two diagnostic groups?
2. To what extent are changes in daily numerical competence (as measured by the NADL) associated with global cognitive functioning? In particular, do reductions in NADL performance correlate with scores on the MoCA? Can the NADL detect specific impairments in numerical functioning that may not be captured by this broader cognitive screening tool?
3. How do numerical impairments relate to language, working and episodic memory, attention, and cognitive reserve in both patient groups? Do declines in NADL performance correlate with performance on the WAB – R part 1 and 2 (language), the digit span forward and backward subtests of the WAIS – R (auditory attention, immediate recall, and working memory), the Picture Sequence Memory Test (episodic memory), and the Cognitive Reserve Index Questionnaire (cognitive reserve)?
4. What is the relationship between structural brain changes and numerical decline in these populations? Do anatomical alterations, such as parietal lobe atrophy, basal ganglia degeneration, or frontal/cingulate involvement at baseline, predict the severity or progression of NADL impairment?

5.How do caregiver and patient-reported difficulties with numerical activities correspond with objective NADL findings? This exploratory question will use the caregiver interview component of the NADL to evaluate the concordance between subjective impressions and formal assessment outcomes.

We hypothesize that these populations will show a different pattern of impairment in the representational codes. We predict that individuals with CBD will show greater impairment on mathematical and quantity-based tasks, whereas individuals with lvPPA will show greater difficulty on tasks that rely more heavily on language-based numerical processing.

*required

Research Design and Methodology

Identify and describe:

- *the overall study approach or methodology (e.g., quantitative, qualitative, mixed methods)*
- *the research design and methods, (e.g., survey, experimental, grounded theory, narrative research, explanatory sequential, etc.)*
- *specific procedures, data collection tools, drugs/devices, etc.*
- *how the data will be analyzed (analytical approach, data handling, software or tools)*
- *how the design and methods will address the research aims.*
- *If the study includes more than one group, arm, or subject population, describe each, and address any randomization or group assignment.*

Prospective participants will be identified through outpatient clinics and hospitals in New York City. Recruitment will be facilitated through collaboration with experienced neurologists, neuropsychologists, and clinicians specializing in frontotemporal dementia and related neurodegenerative disorders.
Individuals with CBD, individuals with lvPPA, and healthy controls will complete a comprehensive neuropsychological battery to evaluate multiple cognitive domains. Testing sessions will be conducted either in person at the Lehman Neurolinguistics Lab or the Graduate Center, or remotely via Zoom. The option to participate remotely will accommodate individuals who are unable to travel to the testing locations, including those who have relocated, and facilitate participation in longitudinal follow-up sessions.
For participants recruited through clinical settings, a HIPAA authorization form will be requested to permit access to relevant medical records. These records may include diagnostic information, clinical history, neuropsychological reports, and available neuroimaging reports or scans relevant to confirming diagnosis and characterizing participants' clinical profiles. The HIPAA authorization form will be included as an attachment to the IRB submission, and medical records will be accessed only after participants provide written authorization.
Global cognitive functioning will be assessed using the Montreal Cognitive Assessment (MoCA; Nasreddine et al., 2005). Mood, feelings, and interests will be measured using the Geriatric Depression Scale (GDS; Yesavage et al., 1982). Language abilities will be evaluated using the WAB-R Parts 1 and 2, including the reading and writing subsections (Kertesz, 2012). Immediate recall and auditory attention will be assessed using Digit Span Forward, and working memory will be assessed using Digit Span Backward (WAIS-R; Wechsler, 1981). Visual memory, attention, and recall will be evaluated using two subtests of the Cognitive Linguistic Quick Test (CLQT). At T1,

participants will also complete the Cognitive Reserve Index Questionnaire (CRIq; Nucci et al., 2018). Following these assessments, participants will complete the Numerical Activities of Daily Living battery (NADL; Semenza et al., 2014).
All sessions, whether conducted in person or remotely via Zoom, will be audio-recorded only to support accurate data collection. During in-person sessions, the testing battery will be administered using an iPad. For remote sessions, testing will be administered through live interaction with the examiner via Zoom, with task presentation and response procedures adapted as appropriate for remote administration. The study will be preceded by a pilot phase involving one to four participants to evaluate the feasibility of the testing procedures.

*required

Participation Duration

How long will subjects participate in the study? Describe the number of and timeline for study visits for research subjects.

Participants will be assessed across three sessions: baseline (T1), three months after the initial session (T2), and six months after the initial session (T3). The total duration of the study is 6 months.

*required

Study End Date

When is the study anticipated to end?

06/01/2027

*required

Data Collection Methods

Select all data collection methods that will be used in this study (check all that apply). Please be sure that all data collection methods are adequately described in Research Design and Methodology.

- ✓ Surveys or questionnaires (without any intervention or stimuli)
- ✓ Interviews (without any intervention or stimuli)

Focus groups (without any intervention or stimuli)

Observational research

Intervention or stimuli with data collection

Sensor or device

Collection of biospecimens (blood, saliva, hair sample, etc.)

Will this study involve genetic testing?

Yes

✓ No

Will any test results be shared with subjects or their providers (e.g., incidental findings, results of standard or research lab tests, genetic test results, etc.)?

Yes

✓ No

Other

Study Instruments

Attach all instruments to be used in the study (e.g., surveys, interview or focus group scripts, personality scales, questionnaires, evaluation tools, etc.).

GDS (short form).pdf

CRIq.pdf

MoCA 8.3 Telemed Instructions - 2020-04-27.pdf

MoCA 8.3 stimuli PP individual stimuli.pdf

MOCA.pdf

Screening questions.docx

Interview with the caregiver.docx

Interview with unhealthy individuals.docx

*required

Does the study involve any FDA-regulated products?

For example, drugs, biologics, devices, diagnostics, dietary supplements, or food additives.

- Yes
- ✓ No

*required

Does the study involve the use of Artificial Intelligence (AI)?

- Yes
- ✓ No

How will AI be used in this study? (check all that apply)

- Data cleaning or preprocessing
- Data analysis or pattern recognition
- Decision support (e.g., recommendations, predictions)
- Predictive modeling
- Natural language processing
- Generative AI (summaries, text generation, embeddings)
- Other

Compensation

*required

Will research subjects receive any compensation for participation?

✓ Yes

No

*required

Select all forms of compensation that will be provided to research subjects:

✓ Monetary (This includes cash, checks or gift cards)

*required

Amount

$40 (total $120 for the three testing sessions)

*required

When will participants receive compensation?

At the end of each testing session

*required

How will compensation be prorated for participants who do not complete all study visits/procedures?

Participants will receive compensation upon completion of each testing session. Participants who withdraw before completing a session will not receive compensation for that session.

Course credit or extra credit

Non-monetary items (e.g. small gifts, tokens)

Raffle

Other

*required

CUNY does not permit the use of personal funds to compensate research subjects. As such, please confirm that the research team has adequate financial support (internal CUNY funds or funding provided through a grant, contract, etc.) to provide this monetary compensation

✓ Yes

No

Research Subjects

Study Inclusion and Exclusion Criteria

Describe the criteria that will make an individual eligible to participate.

For research using secondary analysis of data/biospecimens, describe the criteria for the dataset / specimens.

*required

Inclusion Criteria

Eligible participants need to have a confirmed clinical diagnosis of either CBD (or one of its clinical subtypes, such as probable/possible corticobasal syndrome, frontal behavioral spatial syndrome, progressive supranuclear palsy syndrome) or lvPPA, with diagnostic confirmation supported by neuroimaging evidence (Armstronget al., 2013; Gorno-Tempini et al., 2011). Participants must be in the early stages of cognitive decline (mild neurocognitive disorder as describedin the DSM-5; American Psychiatric Association, 2013). Individuals presenting with only mild cognitive impairment as measured by the Montreal Cognitive Assessment (MoCA; Nasreddine et al., 2005) will be considered eligible. Participants presenting with aphasia will be eligible for inclusion only if the severity of their language impairment is mild as measured with the WAB-R. Patients should have acquired English before age 6. To minimize the influence of affective symptoms on cognitive performance, participants must also score between 0 and 8 on the Geriatric Depression Scale (GDS; Yesavage & Sheikh, 1986). All participants need to have sufficient hearing and vision (corrected if necessary) to complete the study reliably. Only participants living independently or with family/caregivers will be included. As for healthy participants, they should be neurologically healthy, between 50 to 85 years old, they should have learned English before the age of 6, and they should have good hearing and vision (corrected if necessary).

*required

Exclusion Criteria

Participants will be excluded if they do not have a confirmed clinical diagnosis of CBD (or one of its subtypes) or lvPPA. If participants did not acquire English before age 6. Participants in advanced stages of cognitive decline will be excluded, as will those exhibiting moderate to severe aphasia, which may hinder task comprehension or participation. Participants scoring above 8 on the GDS will be excluded to minimize the confounding effects of depressive symptoms on cognitive outcomes. Individuals with severe sensory impairments that interfere with testing procedures will be excluded. In addition, individuals with major comorbid neurological or psychiatric disorders (e.g., Parkinson’s disease, schizophrenia) or unstable medical conditions that could influence cognitive function will be excluded.Finally, participants residing in long-term nursing or assisted-living facilities will not be considered for inclusion. As for the control group, they will be excluded if they are not neurologically healthy, if their age does not fall in the range 50 to 85 years old, if they do not have learned English before the age of 6, and if they do not have good hearing and/or vision.

Recruitment Procedures

*required

Describe how potential participants will be identified, approached, contacted, etc. for recruitment (e.g., when, where, and how potential subjects will be identified and recruited). Identify and describe all recruitment methods (emails, flyers, social media, etc.).

Potential participants will be identified through collaboration with neurologists, neuropsychologists, and other clinicians at outpatient clinics and hospitals in New York City who specialize in frontotemporal dementia and related neurodegenerative disorders. Collaborating clinicians will share IRB-approved recruitment materials with potentially eligible individuals during routine clinical encounters or through established patient communication channels. Interested individuals or their caregivers may contact the research team directly. Alternatively, with the individual's permission, clinicians may provide contact information to the research team for follow-up.

IRB-approved flyers will also be distributed through clinical programs, patient support groups, community organizations, and university networks. The study will be posted through the National Aphasia Association and the FTD Registry to reach potentially eligible individuals and their caregivers beyond local clinical settings.

Healthy control participants will be recruited through IRB-approved flyers distributed through Lehman College and the Graduate Center. Interested healthy volunteers will contact the research team directly and undergo preliminary screening to determine whether they meet the study's eligibility criteria.

All recruitment materials will describe the study's purpose, eligibility criteria, time commitment, compensation, in-person and remote participation options, and research team contact information. Research team members will communicate with interested individuals by telephone or email to explain the study, conduct preliminary eligibility screening, answer questions, and schedule an initial testing session. Both clinical participants and healthy controls may complete testing in person at the Lehman Neurolinguistics Lab or the Graduate Center, or remotely via Zoom. Recruitment will occur throughout the study's enrollment period. Participation will be voluntary, and individuals will be informed that their decision to participate or decline will not affect their clinical care or relationship with the referring institution.

Recruitment Permission

(External organizations, private or restricted websites, listservs, or other third-party platforms)

Recruitment through external organizations, private or restricted websites, listservs, or other third-party platforms may require permission from the site, organization, or administrator. Upload all required permissions.

*required

Recruitment Documents

Upload all recruitment materials used in the study (e.g, flyers, advertisements, telephone scripts, etc.).

Updated Flyer (patients).pdf

Updated Flyer (healthy).pdf

Advertisement - website.docx

Screening Activities

HRPP-111: Criteria for IRB Approval

*required

Will you conduct screening to confirm that subjects are eligible to participate based on inclusion and exclusion criteria?

✓ Yes

*required

Please describe the process that will be used to screen subjects to confirm eligibility to participate.

At the beginning of the first testing session, either in person or online via Zoom, we will conduct a brief screening interview to confirm eligibility. Participants will be asked questions about their demographic information, relevant medical and neurological history, and, when applicable, clinical diagnosis. Their responses will be reviewed against the study's inclusion and exclusion criteria. Only individuals who meet the eligibility criteria will proceed with the study assessments.

Attach all questions and materials that will be used to conduct screening procedures.

Screening questions.docx

No

*required

Subject Enrollment

Enter the number of subjects that will be enrolled in this study.

Total Study Enrollment

Please enter the total number of subjects that will be enrolled at all study sites. If enrollment will occur at multiple sites, please provide a breakdown of enrollment by site.

40

Populations

*required

Special Populations

Please indicate any protected group(s) that will knowingly be enrolled. The help button provides additional information to define some populations.

Adults with Diminished Capacity to Consent

Children

Employees

Students

Economically Disadvantaged Persons

Pregnant Persons & Fetuses

Neonates (birth to less than 1 month)

Non-English Speaking Persons

Prisoners

Other

✓ Not applicable (i.e., enrolling only adults who do not fall into these special populations)

*required

Recruitment and Research Procedures at other CUNY Colleges/Schools

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Will you recruit participants, require data, or need resources from other CUNY colleges/schools?

Yes

✓ No

Participant Protections

*required

Special Procedures

Select whether the study includes any of the following procedures. (check all that apply; select only not applicable if none apply)

- [ ] Covert observation
- [ ] Procedures that might be regarded as an invasion of privacy
- [ ] Procedures which may risk physical/mental harm to the participant
- [ ] Transcranial magnetic stimulation (TMS) and Transcranial direct current stimulation (tDCS)
- [ ] Induction of mental and/or physical stress
- [x] Not applicable this study does not involve any of these procedures

*required

Special Topics

Select whether the study collects information on any of the following topics. (check all that apply; select only not applicable if none apply)

- [x] An individual's psychological wellbeing or mental health
- [ ] use of alcohol, drugs, or other addictive products
- [ ] sexual attitudes, orientation, or practices
- [ ] citizenship or immigration status
- [ ] illegal activities or criminal conduct
- [ ] Questions about suicidal ideation, self-harm history, or suicide attempts
- [ ] Genetic information that may be linked to a participant's health status, such as genetic markers for cancer, heart disease, etc.
- [ ] Health related information which, if disclosed, could reasonably lead to social stigmatization or discrimination

Not applicable this study does not involve any of these topics

*required

Potential Risks

List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related to participation in the research. Consider that the risk of breach of confidentiality is common to almost all research studies.

- *Consider physical, psychological, social, legal, and economic risks, including extra financial costs or time burden the subject may incur from participating.*
- *Describe the probability, magnitude, duration, and reversibility of the risks.*

The risk of conducting this research is minimal. Participants may experience tiredness toward the end of the procedure because they are required to respond to questions.

*required

Risk Mitigation/Reduction

Describe the measures that will be taken to reduce or mitigate the probability or magnitude of risks.

Participants are allowed to take breaks between the various tests.

*required

Potential Benefits

Describe the potential benefits for subjects (if any). NOTE: Payment/compensation should not be described as a benefit to participants.

The research does not give any therapeutic benefit to participants because participants will be tested on their mathematical and numerical knowledge. However, the research will significantly contribute in our understanding of the progression of mathematical and numerical abilities in individuals affected by CBD and lvPPA. This in turn will help clinicians and professionals in tailoring intervention strategies to help

individuals navigate everyday activities involving mathematical and numerical knowledge.

*required

Safety Monitoring

Does this project present greater than minimal risk and include a Data & Safety Monitoring Plan or Data Safety & Monitoring Board/Committee Charter?

- Yes
- ✓ No

*required

HIPAA

The HIPAA Privacy Rule applies to projects where PHI is being obtained, used, or released/disclosed by a Covered Entity for the purposes of Research.

Protected Health Information (PHI) = health information + one or more of the 18 identifiers (see help text).

Does this project involve collecting and/or accessing health information AND one or more of the 18 identifiers?

- ✓ Yes
- No

*required

Does this project involve obtaining, using, or releasing/disclosing PHI by a Covered Entity?

- Yes
- ✓ No

Deception and Incomplete Disclosure

*required

Will the study involve deception?

Deception involves intentionally providing inaccurate or false information to subjects.

Yes

✓ No

*required

Will the study involve incomplete disclosure?

Incomplete disclosure involves withholding information about some aspect of the research, whether in the procedures or the purpose of the research.

Yes

✓ No

Informed Consent

Each adult research subject or their legally authorized representative must provide full informed consent unless the CUNY UI-IRB approves a Waiver or Alteration of Informed Consent. Consent must be documented with the subject's signature unless the CUNY UI-IRB approves a Waiver of Documentation of Informed Consent.

HRPP-109: Consent Process and Documentation

*required

Plans to obtain informed consent from adult subjects.

✓ **Subjects will provide informed consent and will sign a consent form.** The consent form will include all required elements of consent and all relevant additional elements, and will be signed by the subject.

Subjects will provide consent, but will not sign a consent form.

Requesting a waiver of consent for some or all subjects

Requesting an alteration of consent for some or all subjects. (Select this option if the study involves deception or incomplete disclosure.

*required

Consent Process

Describe the procedures for obtaining informed consent.
If vulnerable populations are included, specifically address how consent will be obtained for such populations. If any waivers or alterations are noted above, describe them, noting any differences between subject groups, procedures, study arms, etc.

Informed consent will be obtained before any study-specific screening or testing procedures begin. We will review the consent form with each prospective participant, explaining the study's purpose, procedures, three-session schedule, audio recording, potential risks and benefits, compensation, and confidentiality protections. Participants will have time to review the information and ask questions. They will be informed that participation is voluntary and that they may decline or withdraw at any time without penalty or loss of benefits to which they are otherwise entitled.
For in-person participation, the consent discussion will take place in a private setting at the testing location, and participants will sign the consent form before study procedures begin. For remote participation, the consent form will be provided in advance and reviewed with the participant during a live Zoom meeting. Written consent will be documented through signature by returning a signed copy before screening or testing begins. All participants will receive a copy of their completed consent form.
For participants with CBD or lvPPA may have communication or cognitive difficulties, the consent discussion will use clear language, additional processing time, repetition, and written or visual supports as needed. A caregiver or support person may attend at the participant's request, but the participant's own understanding and voluntary decision will guide the consent process. If a participant cannot demonstrate adequate understanding despite these supports, enrollment will not proceed.
Willingness to continue will be confirmed at each subsequent session. If concerns about a participant's ability to provide ongoing consent arise, study procedures will be paused. When access to medical records is requested, a separate HIPAA authorization will also be obtained before those records are accessed.

Consent & Assent Form(s)

Attach all consent forms, assent forms, and parental permission forms. Use the applicable CUNY Consent Form Template.

Informed Consent (patients).docx

Informed Consent (healthy).docx

*required

Audio/Video Recording or Photographs

Does the study involve using audio or video to record subjects, or taking photographs of subjects?

✓ Yes

*required

Please select the method(s) that will be used (check all that apply)

✓ Audio recording

Video recording

Photographs

Other

*required

Please describe the purpose of the audio recording, video recording, and/or photography.

The purpose of the audio recording is to ensure accuracy of data collection.

No

*required

Subject Privacy & Confidentiality

Describe the steps that will be taken to protect subjects' privacy during all activities, including recruitment, consent and data collection procedures.

If using video conferencing platforms, describe measures to protect privacy while using these platforms.

During the recruitment process, no personal or identifying information will be collected until a potential participant voluntarily contacts the research team. Recruitment communications will occur through secure institutional email. When recruitment occurs in clinical settings, potential participants will be approached privately.
The informed consent process will be conducted in a private setting at Lehman College or the Graduate Center, or remotely via Zoom. For remote participation, participants will receive two copies of the consent form by postal mail, along with a prepaid, addressed return envelope. We will review the consent form with the participant during a live Zoom meeting and answer any questions. Participants who agree to participate will sign and return one copy using the prepaid envelope and retain the second copy for their records. The research team must receive the signed consent form before any study-specific screening or testing begins. No consent discussions will be recorded.
For remote consent discussions, the researcher will connect from a private room and ask participants to join from a quiet, private location. Screen sharing during the consent discussion will be limited to the consent form.
All research activities will be conducted in a manner that safeguards participants' privacy. In-person testing sessions will take place in private rooms at the Lehman Neurolinguistics Lab or the Graduate Center. Remote testing sessions will be conducted live via an institutionally approved Zoom account, with passcode protection and a waiting room to restrict access. Meeting links will be shared directly with participants through institutional email. Researchers will conduct sessions from a private room and ask participants to join from a private location and, when feasible, use headphones.
Participants will be reminded not to include identifying details in their responses. With participants' consent, testing sessions conducted in person or via Zoom will be audio-recorded. Access to audio files will be restricted to authorized research team members, and files will be stored on password-protected, encrypted institutional folders. Identifiers in study data will be replaced with unique participant codes, and the code key will be stored separately from the research data.

*required

Data/Specimen Security

Describe your plan for maintaining the confidentiality of study data and/or specimens.

Please address the following:

- *Where data/specimens will be stored;*
- *How data/specimens will be stored (including password protecting and encrypting data);*
- *Who will have access;*
- *Data/Specimen retention plan for physical and electronic data (including consent forms, if applicable); and,*
- *What will be done with the data/specimen after the study is closed and the minimum three-year data storage period has been met.*

Keep in mind

- *CUNY PIs are required to use CUNY issued devices / password-protected computers and online accounts only for research data.*
- *[For Student Research] Faculty Advisors are active mentors to Student Researchers and share responsibility for ethical conduct of the research and compliance with applicable laws, regulations and CUNY policies. Faculty Advisors and Student Researchers are required to make arrangements to ensure the data is stored for the minimum 3-year requirement.*

All study-related data—including consent forms, coded participant files, and any audio recordings—will be stored on CUNY-issued, password-protected devices and within secure, encrypted institutional storage systems (e.g., CUNY OneDrive, CUNY Dropbox, or other university-approved encrypted servers). No identifiable or research data will be stored on personal computers, unencrypted drives, or external cloud platforms. Electronic data will be stored in password-protected folders accessible only to authorized members of the research team. Any hard copy materials (e.g., signed consent forms, field notes) will be kept in a locked filing cabinet within a locked office on CUNY premises (i.e., the Lehman Neurolinguistics Lab). Only the Principal Investigator and the Faculty Advisor will have access to the data. In compliance with CUNY policy and federal regulations, all research data will be retained for a minimum of three years following the official study closure.

*required

Digital Platforms and Data Collection Tools

What online instruments, tools, platforms, or technologies will be used in this study?

Please check all that apply:

- ✓ CUNY Dropbox
- ✓ CUNY OneDrive
- CUNY Qualtrics
- ✓ CUNY Zoom/Microsoft Teams
- Social Media Platforms
- M-Turk
- Prolific
- Custom or institution-built web applications
- Other online tools or technologies

*required

Will identifiable information be collected or stored via online instruments, tools, platforms or technologies?

Yes

✓ No

Not sure

*required

Data and Specimen Storage

How will the research data/specimens be stored?

With participant direct identifier(s): Select this option if the data/specimens will, at any time, contain direct identifiers.

✓ **With codes**: *Coded data is information where direct identifiers (likes names or ID numbers) will be replaced with a unique code that allows researchers to re-identify subjects using a key/coded list.*

*required

Describe how data will be coded

Each participant will be assigned an alphanumeric code (e.g., CBD1, CBD2, PPA3) that will be used in place of their names or any other identifying
information on all research materials, including transcripts, test results, and data files.

*required

Indicate where links to codes will be stored.

The master code key, which links participant names and contact information to their assigned codes, will be stored separately from the research data in a password-protected and encrypted file on a CUNY-issued, password-protected computer. Only the Principal Investigator and Faculty Advisor will have access to this key.

*required

List the identifier(s) that will be stored:

Alphanumeric codes (e.g., CBD1, CBD2, PPA3)

*required

Will codes be deleted (and data anonymized) at a later date?

Yes

✓ No

Without any identifiers or codes: Select this option if the data/specimens will never, at any time or in any location, contain direct identifiers or be linked to identifiable information via a code list.

*required

Will you share data/specimens with non-CUNY researchers?

Yes

✓ No

*required

What will you do with the data/specimens once the research has been completed. (check all that apply)

Researchers must obtain explicit consent from participants before using their data/specimens for any purpose beyond the current study. Please refer to the Future Use section in the Additional Language for the Simplified Consent Form Template for required consent language and disclosure elements.

HRPP 109: Consent Process and Documentation
HRPP 201.3: Additional Language for Simplified Consent Form Template
HRPP 306: Research Use of Identifiable Private Information and/or Identifiable Biospecimens

✓ Data /specimens will not be shared or stored for future use. Data/specimens will be retained for three years, or longer when required by the study sponsor, then destroyed.

Data/specimens will be stored for potential future use and/or sharing.

Data/specimens will be submitted to an existing data/bio bank.

Other Attachments

Use this section to upload any required documents that do not have a designated attachment field elsewhere in this application.

Attachments

Other Attachments

digit span test.pdf

NADL_ENG.DOC

English WAB-R Part 1.png

English WAB-R Part 2.png

Adjunct Faculty

Documentation of Provost approval for the adjunct faculty member to serve as PI on this project.

Adjunct faculty member's CV.

Completed form HRPP-113.1: Adjunct Faculty Request to Serve as PI.

Documentation of CITI Training in Human Subjects Research for these personnel.

Independent Researchers

Independent Researcher Agreement(s)

Training Documentation for Independent Researchers

IRB Oversight CUNY Relying on Another IRB

Consent/Assent Forms

Study Documents

Reviewing IRB Approvals

Reliance Agreements

Proposal and Award Documents

Fw: DSRG: Congrats!.pdf

Study Instruments

GDS (short form).pdf

CRIq.pdf

MoCA 8.3 Telemed Instructions - 2020-04-27.pdf

MoCA 8.3 stimuli PP individual stimuli.pdf

MOCA.pdf

Screening questions.docx

Interview with the caregiver.docx

Interview with unhealthy individuals.docx

118 Determination Supporting Documentation

Secondary Analysis of Data or Biospecimens

Additional International Research Documentation

Data Use Agreement, Material Transfer Agreement, etc.

Recruitment Permission

Recruitment Documents

Updated Flyer (patients).pdf

Updated Flyer (healthy).pdf

Advertisement - website.docx

All questions and materials that will be used to conduct screening procedures.

Screening questions.docx

All Translated Materials

Documentation of permission from each CUNY College/School

Study-Specific Capacity Assessment Tool

Preclinical Studies - Supporting Documents

Debriefing Script

Consent & Assent Form(s)

Informed Consent (patients).docx

Informed Consent (healthy).docx

CUNY CIS Permission

Data Use Agreement

Data Transfer Agreements (Data/Bio Bank)

FDA Insurance Letter

Drug/Biologic/Food/Cosmetic Documentation

Device Documentation

FERPA Release Form

FERPA Institutional Permission

HIPAA Authorization Document

hippa form.pdf

Additional HIPPA Documentation

DSMP Documentation

Department of Defense: Permission to Recruit on Military Installation

Department of Defense: Human Research Protection Office (HRPO) Approval

Department of Defense: Scientific Merit Document

Department of Justice: Attach the Privacy Certificate

Department of Justice: Federal Bureau Research Review Board (?BRRB?) Approval Letter/Permission from Warden

National Institutes of Health: Data Sharing and Management Plan (DSM)

Legacy Attachment(s)

Please attach a pdf of the most recent approved IRBManager package.

Protocol Form-2026-08-17-13-18.pdf