

Mesulam Center for Cognitive Neurology and Alzheimer's Disease

Guidelines and Policies for Collaborating with the Mesulam Center

Statement

The Mesulam Center for Cognitive Neurology and Alzheimer's Disease houses multiple resources for collaborative research on cognitive aging and dementia. These include well-characterized cognitively normal or cognitively impaired research participants, neuropathologic specimens, blood samples, neuroimaging, and other biomarker data, and cognitive and behavioral data, many of which are collected longitudinally. All applications for collaboration are reviewed by the Mesulam Center's Executive Committee, which evaluates the applications for scientific merit and justification, the likelihood of research leading to publications and/or grant applications, source of funding for the proposed study (NIH is priority), and availability of the requested resources. All collaborators are requested to share data as appropriate with the Center.

Purpose

The purpose of this document is to outline a process for an effective and mutually beneficial collaboration. The document has been developed to promote efficiency and accountability and minimize risks.

Audience

This document applies to any individual or entity that wishes to collaborate with the Mesulam Center. Collaboration includes, but is not limited to, sharing of resources, letters of support, input on grant applications, and more basic interactions for research planning.

Impact of COVID-19

Due to the COVID-19 pandemic, the Mesulam Center was unable to complete in-person research visits with research participants. The Mesulam Center has slowly started to bring research participants back for in-person visits. At this time, we will not be referring human participants to collaborative studies. We plan to re-evaluate this policy in September 2021.

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Mesulam Center Contacts for Consultations & Collaborative Applications

To prevent delays in considering your application, please contact one or more of the Mesulam Center faculty listed below (as appropriate for your study) to begin a dialogue about your application for feasibility, scope, and collaboration well in advance of any schedule limitations you may have.

It is required that you discuss your study with someone from the Mesulam Center to prevent submission of applications that are not feasible, for which there are no resources, or for which a Mesulam Center collaborator has not been identified before submission. If the scope of the application requires substantial faculty and staff effort and resources for processing the requested materials, this would need to be taken into consideration as early as when you are planning your research proposal. Applications can be submitted once your Mesulam Center collaborator(s) has given approval.

Please allow at least six weeks for the review of your application. To facilitate a timely review, please ensure that all sections of the application are complete. Complete applications are discussed at the monthly Executive Committee meeting, which typically occurs on the second Thursday of the month. You should expect a response (approved, approved with limitations, rejected, not reviewed, request for modification) within approximately two weeks of Executive Committee review (i.e., 4-6 weeks after you submit the application, so planning ahead is critical).

Due to COVID-19, there may be unexpected delays.

PLEASE REMEMBER – Failure to consult with Mesulam Center faculty before submitting your application will result in delays in reviewing or approving your application. Incomplete applications will also result in delays in reviewing or approving your application.

Resources Available

The Mesulam Center is home to one of over 30 Alzheimer's Disease Research Centers (ADRCs) funded by the National Institute on Aging (NIA). In addition, the Center houses several major funded studies investigating the heterogeneity of cognitive aging and dementia. Data obtained through the ADRC are contributed to the National Alzheimer's Coordinating Center, housed at the University of Washington in Seattle. As part of this group, the ADRC administers a standardized set of procedures, known as the Uniform Data Set (UDS). For more details on what variables are available through our ADRC, please refer to the [National Alzheimer's Coordinating Center](#). To collaborate with the other major funded projects at the Center that follow specific populations [e.g., SuperAgers, behavioral variant frontotemporal dementia (bvFTD), primary progressive aphasia, (PPA)], the same procedures are required for approval, and resources can be discussed with your proposed Mesulam Center collaborator(s).

1. Human Research Participants (age range 50-90+)

If your study requires human participants for novel behavioral and/or neuroimaging data collection please contact [Sandra Weintraub, PhD](#) (ADRC Clinical Core leader), [Tamar Gefen, PhD](#) (ADRC Assistant Clinical Core leader), [Emily Rogalski, PhD](#), (ADRC Neuroimaging Biomarker Core leader and PI for SuperAger and PPA projects) and/or [Marsel Mesulam, MD](#) (Mesulam Center Director, PI for PPA projects). If you are conducting a study that requires study partners or caregivers, please contact [Darby Morhardt, PhD](#) (ADRC Outreach, Recruitment and Education Core leader). You may also request available participant data for your study once approved.

Types of Available Research Participants (age range ~50-90+)

- a. Cognitively healthy controls
- b. Enrollment in our patient registry emphasizes patients diagnosed with Mild Cognitive Impairment (MCI) or several forms of dementia, including amnesic dementia of the Alzheimer type, behavioral variant frontotemporal dementia, and primary progressive aphasia.
- c. Study partners/caregivers of cognitively healthy and impaired participants.

2. Neuropsychological Data on Human Research Participants

The Neuropsychological Battery of the Uniform Data Set is available in two forms, version 2.0 (used from 2008 up until 2015) and version 3.0 (used since March 2015 to present time). For the neuropsychological measures below, one asterisk indicates a UDS 2.0 measure only, and two asterisks indicate a UDS 3.0 measure only. A crosswalk study was completed to allow investigators to compare scores from both forms. For more information on the UDS, please visit the [National Alzheimer's Coordinating Center](#).

- a. Mini-Mental State Exam (MMSE)*
- b. Montreal Cognitive Assessment (MoCA)**
- c. Logical Memory (immediate and delayed)*

- d. Craft Story 21 (immediate and delayed)**
- e. Benson Complex Figure Copy (immediate and delayed)**
- f. CERAD Constructional Praxis*
- g. Number/Digit Span (forward and backward)**
- h. Digit Span (forward and backward)*
- i. Category fluency (animals and vegetables)
- j. Trail Making Test (parts A and B)
- k. Multilingual Naming Test (MiNT)**
- l. Boston Naming Test (BNT)*
- m. Verbal Fluency: Phonemic Test (F and L)**

Additional Northwestern measures available on subsets of ADRC participants:

- a. Rey Auditory Verbal Learning Test (RAVLT)
- b. American version of the National Adult Reading Test (AMNART)

3. Clinical Data on Human Research Participants (collected in versions 2 and 3 of the UDS; see [National Alzheimer's Coordinating Center](#) for full descriptions of data and collection methods.

- a. Demographics (e.g., age, race, sex, education, etc.)
- b. Participant family history
- c. Participant medication
- d. Participant health history
- e. Physical information at time of visit (e.g., height, weight, BP, heart rate, eyesight and hearing status)
- f. Clinical Dementia Rating Scale (CDR® Plus NACC FTLD)
- g. Neuropsychiatric Inventory Questionnaire (NPI-Q)
- h. Activities of Daily Living Scale (ADL-Q)
- i. Functional Activities Questionnaire (FAQ)
- j. Geriatric Depression Scale (GDS)
- k. Neurological exam findings
 - i. Parkinsonian signs
 - ii. Neurological signs considered to be consistent with cerebrovascular disease
 - iii. Higher cortical visual problem suggesting posterior cortical atrophy
 - iv. Findings suggestive of progressive supranuclear palsy, corticobasal syndrome or other related disorder
 - v. Findings suggestive of ALS
 - vi. Normal-pressure hydrocephalus: gait apraxia
 - vii. Other findings
- l. Clinician judgment of symptoms
 - i. Cognitive symptoms (e.g., memory, orientation, language)
 - ii. Behavioral symptoms (e.g., apathy, depressed mood, disinhibition)
 - iii. Motor symptoms (e.g., gait disorder, falls, tremor)
 - iv. Overall course of decline or predominant domain
- m. Clinical diagnosis
- n. APOE genotype

4. Tissue or Biospecimens

All materials banked in the Alzheimer's Disease Research Center (ADRC) Neuropathology Core or one of the other laboratories in the Mesulam Center remain under the authority of the Executive Committee. Questions regarding available tissue and biospecimen resources can be directed to [Margaret Flanagan, MD](#) (Northwestern ADRC Neuropathology Core Leader) or [Changiz Geula, PhD](#) (Director of the Laboratory For Cognitive and Molecular Morphometry).

Tissue Requests Disclaimer: No screening for infectious agents has been performed on tissues or bodily fluids provided by the ADRC. The investigator must take appropriate precautions.

- a. Fixed brain tissue
- b. Frozen brain tissue
- c. Unstained brain sections
- d. DNA
- e. Plasma
- f. CSF (limited)
- g. Neuropathologic findings (e.g., neuropathological diagnoses, BRAAK tangle stage, CERAD neuritic plaque density score)

5. Neuroimaging Raw and Processed Resources

If your study is based on accessing already collected raw or processed neuroimaging data, please contact ADRC Neuroimaging and Biomarker Core leader [Emily Rogalski, PhD](#).

- a. Structural MRI (sMRI)
- b. Resting state MRI (rsMRI)
- c. Diffuse Tensor Imaging (DTI)
- d. FLAIR Imaging
- e. Amyloid PET
- f. FDG PET
- g. Tau PET

6. Data

For consultation and requests for studies analyzing already collected neuropsychological, clinical or neuropathologic data, please consult with the relevant Mesulam Center faculty collaborator (e.g., Clinical Core for neuropsychological data; Neuroimaging Biomarker Core for neuroimaging studies, Neuropathology Core and Molecular Morphometry Lab for neuropathologic data, etc.). Once your study has been discussed with your Mesulam Center collaborator(s) and approved, you will be connected with our data management group to access the data you require. You may also consider involving the Biostatistics and Data Management Core if you need consultation regarding study design for a grant proposal using ADRC resources. [Hui Zhang, PhD](#) is the ADRC Biostatistics Core co-leader.

Important Dates and Timelines

1. The Mesulam Center Executive Committee Approval Timeline

The Mesulam Center Executive Committee reviews and approves all collaborative applications. Please allow at least six weeks for the review of your application. All collaborative applications must be submitted at least two weeks before the Executive Committee meeting to be reviewed at that month's meeting. The committee typically meets on the second Thursday of the month. **Submission dates may change due to holidays so please check the [website](#) to make sure you are aware of the annual schedule of meetings.** If your collaborative application is not submitted on time its review and approval may be delayed until the following month. Your application must be submitted with all necessary materials to avoid any delay in reviewing it.

2. Time Limitation of Requests

Unless approved for a longer period of time, all applications are considered "active" for a maximum of 18 months. The approval is good only for the stipulated study and resources cannot be reused for other purposes without a separate collaborative application. Even if you are conducting a different analysis in addition to that you proposed and will submit it as a separate paper, our funding relies on our reporting of all papers, studies and grants that utilize our resources. Extensions beyond 18 months may be requested and will be reviewed by the Executive Committee.

Procedures for Submitting Collaborative Requests

1. Pre-Submission of Collaborative Application

Before collaborative application submission, please ensure you have already discussed your study and application with the appropriate Mesulam Center faculty person(s), as noted above. Your application may not be considered feasible and this will avoid needless completion of the application. It is also critical that you have read through this entire policy before submission and are fully able to accept the conditions. Please also have the following materials ready before starting your application: IRB approval or exemption letter, consent form (for human participants), funding source/ information, project aims, preliminary work that shows justification for your project, etc. Applications are submitted online through a public REDCap survey, but you may view a PDF of the application [here](#).

2. Online Completion of Collaborative Application

The Mesulam Center collaborative application can be completed [here](#). Please ensure you have all the necessary materials to complete the application in full. You should receive an email following your application submission confirming we have received the application. The application will be distributed to the Executive Committee for review.

3. Post Application Submission

After your application submission, you may be contacted by your Mesulam Center faculty person(s) to clarify, edit, or update your application before its presentation at the Executive Committee meeting. The Mesulam Center will work with you to ensure your application is approved in a timely manner. However, please remember if your application is not submitted 14 days before the Executive Committee meeting or is incomplete, it will not be reviewed at that month's meeting.

4. My application was not approved: Now what?

We receive many requests for collaboration and your application may be turned down by the Mesulam Center Executive Committee for a variety of reasons. You may choose to submit a new application based on the feedback received. More information on why applications are not approved is below.

- a. Applications are judged based on scientific merit and the likelihood of leading to publications or grant submissions. If these are deemed lacking, the application may be turned down.
- b. Some applications are rejected because we don't have the resources you request.
- c. Some applications are not reviewed because there is insufficient information to allow for an evaluation.
- d. Some applications requiring the involvement of human research participants are rejected because procedures are deemed too burdensome for our participants who may already be enrolled in more than one study. One category of patient participant that is in high demand, for example, is amnesic mild cognitive impairment and participant burden is a major consideration for this cohort.
- e. The request conflicts with other studies we are already supporting or proposed procedures would have an impact on the outcome of other studies in which participants eligible for your study are already enrolled (e.g., several of our studies use the Rey Auditory Verbal Learning Test so any study that needs to use this measure or administer it on multiple occasions would interfere with ongoing projects).
- f. Some requests exceed the scope of our usual involvement by requiring time and effort beyond that supported by our grant. If our resources entail time and effort to provide materials central to your project or application (e.g., you are planning to obtain all or most of your tissue samples from our brain bank laboratory), you may consider planning with your Mesulam Center collaborator(s) for support well in advance, which may also entail a supporting role in your proposal if appropriate and feasible for the collaborator(s).

5. Approval of Application

If your application is approved by the Mesulam Center Executive Committee, our collaborative agreement will be emailed to you via a REDCap link or PDF letter. You must sign the collaborative agreement before resources are shared. The collaborative agreement specifies our policies on acknowledgments and authorship, annual reporting guidelines as well as data use. Please note your application may be approved with

limitations or partially approved. If it is partially approved, we will specify the limitations. You will be provided with a list of funding award numbers (R01, P30, etc.) and acknowledgments to include in any publications for the resources that will support your study. Once your signed collaborative agreement is received, your Mesulam Center collaborator(s) will be notified so they begin working with you to share resources. Please also note that it can take days to weeks to fulfill your collaborative needs. We do ask that you exercise patience with our staff and faculty.

Mesulam Center Collaborative Agreement

If your application for collaboration with the Mesulam Center is approved or partially approved, you must agree to our collaborative agreement (see example below) before any resources can be shared. Additional elements may be added to the agreement depending on the nature of the collaboration.

1. I will acknowledge the relevant ADRC Core (Clinical Core, Imaging Core, and/or Neuropathology Core) and/or other grant resources (e.g., PPA, SuperAging, etc.) in all publications, abstracts, and presentations. I will ensure the grant number(s) is listed as required by the NIH and linked to entries into PubMed. The Mesulam Center will provide me with the appropriate grant number(s) to be listed in my publications, abstracts, and presentations. An example of acknowledgment is below.

This study was supported in part by an Alzheimer's Disease Core Center grant (P30 AG013854) from the National Institute on Aging to Northwestern University, Chicago Illinois. We gratefully acknowledge the assistance of the Clinical Core and its participants.

2. I will send a copy of any manuscripts, and abstracts, at least two weeks before submission to determine, on a case-by-case basis, what Center authorship (if any) is appropriate. Co-authorship is based on the usual metrics.
3. I will provide the Mesulam Center with a list of all abstracts, publications, or grant applications that have emanated from the use of resources. If applicable, I will also provide the Mesulam Center with outcomes on the participants referred for my project. At a minimum, I will provide this information annually when I receive a request for this information.
4. I will use these data and/or recruit participants only for the project stated in my approved collaborative agreement. I will not use the data and/or participants for another project or share the data or participant contact information with other researchers.
5. If I have been referred human participants, I will use the script provided for contacting referred participants to minimize confusion. If there are any issues with a human participant (e.g., they can't recall being in a study at Northwestern or they have grievances) I will immediately notify the Mesulam Center for assistance.
6. I understand that this agreement is approved for up to 18-months and I will need to apply for an extension if the project exceeds this time frame. If my findings lead to a follow-up experiment and resources are required again, I will submit a new collaborative application.

Authorship and Right of First Refusal

The effort and resources entailed in maintaining a collaborative resource such as ours are significant. Depending on the nature of the request and the effort involved before and during the fulfillment of the request, authorship inclusion will be weighed. There is a tremendous effort involved in recruiting human participants, characterizing them neurologically and cognitively, collecting blood, and following them longitudinally. These efforts must be recognized by including relevant authors as determined by the Executive Committee. The Mesulam Center faculty has the right to accept or refuse authorship.

Use of ADRC Human Participants or Their Data

Projects using human participants from the Mesulam Center, their brain tissue, or data derived from such participants, must obtain approval from [Northwestern University's Institutional Review Board](#). Multi-year studies should forward copies of renewed IRB approval annually to ADC@northwestern.edu. Failure to provide IRB approval will delay your access to Mesulam Center resources.

Please include language in your consent form that permits the future use of the data you collect (e.g., "Your data may be used by the research team now and in the future to answer questions about health concerns, aging, memory, and thinking.") Also include the statement "The data collected in this (your) study will be shared with other researchers via data sharing agreements that protect the identity of the participant." You may not share the data provided by the Mesulam Center with other researchers. If such sharing is required, that researcher must submit their own independent collaborative application for the data. This is our only method of fully tracking the utilization of resources. If your request involves archival data or tissue, approval or exemption from the IRB is still required (e.g., analyses of computerized images or re-analysis of previously collected data to answer a new question). If any clinical information is to accompany autopsy tissue, IRB approval may be required for your project. Please check with the IRB.

It is a violation of University policy, HIPAA, and our ADRC Human Studies approval to link participants' names and scores in any way. ALL INDIVIDUAL DATA MUST BE STORED BY ADRC PARTICIPANT ID NUMBER, not name or participant's initials. Should a second unique identifier be necessary as a cross-check, please consult with your Mesulam Center point person. Any communication (with the ADRC or anyone else) should use participant ID numbers, never names. If you have solely been provided data, no attempt should be made to re-identify participants using their data.

All researchers must abide by the IRB guidelines regarding the securing of participant names. In the collaborative application, indicate how you will preserve confidentiality; your approval is dependent on this.

Collaborator orientation to use human research participants – Before you contact any of our participants, you will receive guidance from Mesulam Center staff for contacting and interacting with them. This is done to avoid participants' confusion and ensure a warm referral.