Mesulam Center for Cognitive Neurology and Alzheimer's Disease

Guidelines and Policies for Collaborating

Contents

Overview

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 their 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 planning for research projects.

Collaborators at the Mesulam Center

Before applying to collaborate, it is required that you discuss your study with someone from the Mesulam Center. This prevents submission of applications that are not feasible (e.g., resources are not available). To prevent delays in considering your application, please contact one or more of the Mesulam Center faculty (as appropriate for your study) to being dialogue about your application for feasibility, scope, and collaboration well in advance of any deadlines you may have. A full list of all Mesulam Center faculty collaborators can be found on our website here. More information about the Mesulam Center faculty is included throughout this document.

Failure to consult with a faculty member before submitting your application WILL result in delays in reviewing your application. Incomplete applications will be returned for completion prior to review. **Applications can be submitted once your Mesulam Center collaborator(s) has given approval.**

Resources Available

The Mesulam Center is home to one of over 33 Alzheimer's Disease Research Centers (ADRCs) in the country funded by the National Institute on Aging (NIA). In addition, the Mesulam 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 (NACC), 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 NACC's website (https://naccdata.org/).

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). Resources available at the Mesulam Center are listed below (1-6).

1. Human Research Participants

Human participants at the Mesulam Center typically range from 50-90+ years old. If your study requires human participants for a variety of studies including novel behavioral and/or neuroimaging data collection, please contact one or more of the following individuals:

- Sandra Weintraub, PhD (ADRC Clinical Core Leader, SuperAger Associate Director)
- Tamar Gefen, PhD (ADRC Clinical Core Co-Leader)
- Elena Barbieri, PhD (Associate Director for PPA Programs)
- Darby Morhardt, PhD (ADRC Outreach, Recruitment, and Education Core Leader) – should be contacted for studies that require caregivers and/or study partners

The types of research participants available include:

a. Cognitively healthy controls
b. Patients diagnosed with Mild Cognitive Impairment (MCI) or one of several forms of dementia (e.g., amnestic dementia of the Alzheimer Type, bvFTD, PPA)
c. Caregivers/study partners of cognitively healthy or cognitively impaired participants.

You may request available participant data for your study once approved. **More information regarding the use of ADRC Human Participants and/or their data can be found in Appendix A. Please review this before submitting a collaborative request.**

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 to 2015) and version 3.0 (used since March 2015 to present). Please view Appendix B to review all available neuropsychological measures.

3. Clinical Data on Human Research Participants

Clinical data was collected in version 2.0 and 3.0 of the UDS. Please view Appendix C to review all available clinical data variables.

4. Tissue or Biospecimens

All materials banked in the ADRC Neuropathology Core or one of the other laboratories in the Mesulam Center remain under the authority of the Executive Committee. If your study requires tissue or biospecimen resources, please contact one or more of the following individuals:

- Rudolph Castellani, MD (ADRC Neuropathology Core Leader)
- Changiz Geula, PhD (Director of the Laboratory for Cognitive and Molecular Morphometry)

All tissue or other biospecimen are available in different quantities. Please discuss amount needed for your study with the Mesulam Center collaborator prior to submitting an application. Failure to do so could result in your application being denied. The following types of resources are available:

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)

**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.

5. Neuroimaging Raw and Processed Resources

If your study is based on accessing already collected raw or processed neuroimaging data, please contact Todd Parrish, PhD (ADRC Neuroimaging and Biomarker Core leader). The following types of resources are available:

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. Once your collaborative request has been 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

Mesulam Center Executive Committee Timeline

The Mesulam Center Executive Committee reviews all collaborative applications. Collaborative applications must be submitted at least two weeks prior to an Executive Committee meeting to be reviewed at that month's meeting. The Committee typically meets on the third 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. Your application must be submitted with all necessary information

to avoid any delay in reviewing it. Please allow at least six weeks for the review of your application after we receive it.

Time Limits for Requests

Unless otherwise specified, all approved 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 the one 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.

Process for Submitting a Collaborative Request

1. Pre-Submission of Collaborative Application

Before submission of your collaborative application, as noted above, please discuss your request with the Mesulam Center collaborator that you have identified. Please also have the following materials ready before starting the application:

a. IRB approval or exemption letter
b. Consent form (for human participant request)
c. Funding source/information
d. Project aims
e. Preliminary work that shows justification for your project

You can view a PDF of the application on our website.

2. Submission of the Collaborative Application

Applications are submitted through a REDCap survey, which is linked on our website. You may also click here. Once submitted, you will receive an automated email that confirms we have received your application.

3. Mesulam Center Executive Committee Review

Once submitted, the Executive Committee will review your application. You may be contacted by your Mesulam Center collaborator to clarify, edit, or update your application. This may happen either before or after your submission. These updates may cause review of your application to continue at the next month's Executive Committee meeting.

4. Collaborative Application Decision Returned

Application is approved

If your application is approved by the Mesulam Center Executive Committee, our collaborative agreement (example in Appendix D) will be emailed to you via a REDCap link. 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 so that you plan sufficient time.

Application is denied

Please review the reason your application was denied. You may choose to submit a new application based on the feedback you received. Your application could be denied for a variety of reasons, including:

a. Application is deemed to be lacking scientific merit or likelihood of leading to a publication or grant submission is deemed low.
b. We don't have the resources requested.
c. Application was not reviewed because there is insufficient information to allow for an evaluation.
d. Procedures are deemed too burdensome for our Human Research Participants who may already be enrolled in more than one study.
e. Study 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. Request exceeds 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 providing grant/personnel support for the activities.

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.

Questions?

For questions about the application process, please contact adc@northwestern.edu. You can also view information about collaborating on our website at https://www.brain.northwestern.edu/.

Appendix

Appendix A

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 unique ID number, not name or participant's initials.** This unique ID number will be provided to you upon data sharing from the Mesulam Center. Any communication (with the ADRC or anyone else) should use unique 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.

Appendix B

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 NACC's website (https://naccdata.org/).

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)

Appendix C

For full descriptions of data and collection methods, please visit NACC's website (https://naccdata.org/).

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

Appendix D

Example of language that will be included in an approval letter which collaborators MUST sign before resources are shared.

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 (i.e., screened, recruited, not recruited). 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.