

# Mesulam Center Collaborative Application

## COVID-19 COLLABORATIVE UPDATES

Due to the current COVID-19 outbreak, all collaborative applications requesting biospecimens, such as brain tissue or blood samples, will be reviewed, but may not be approved or may be approved with limitations. Additionally, most Mesulam Center human participant studies have suspended in-person visits. For the safety of our participants, we would like to resume our in-person visits before referring our participants to collaborative studies. Because of this, all collaborative applications requesting human participant referrals should expect delays in receiving referrals. If you have any questions or concerns, please discuss them with your Mesulam Center collaborator(s) before completing the application below.

## POLICY FOR AUTHORSHIP, ACKNOWLEDGEMENT, AND DATA SHARING ON COLLABORATIVE PROJECTS

The Mesulam Center contains multiple resources for researchers including well-characterized research participants, neuropathologic specimens, neuroimaging data and other biomarker data, and cognitive and behavioral data. The following is our policy regarding collaboration and access to our resources:

1. An annual report will be requested in the beginning of each year, including a list of all abstracts, publications, grant proposals, and any other product directly dependent on the use of our participants, data, and/or samples. If your study involves human participants, we will request quarterly updates on the outcomes of referrals to your study.
2. The Mesulam Center must be acknowledged in all publications, abstracts and presentations. In addition, you will be asked to acknowledge the funding source relative to your particular collaboration. Once your project is approved, you will be sent a list of relative funding sources.
3. A copy of any manuscripts and publishable abstracts must be submitted for review by our Center Executive Committee prior to submission so that we may determine what Center authorship and attribution is appropriate. We will respond within a week of receipt of the manuscript.
4. We may request that you share relevant data from your study on our participants to supplement our existing data (e.g., MRI volume and data, genetic testing outcomes, etc.). Please make sure your IRB documents contain the appropriate language for sharing your data with our Center.

We have been very successful in working with collaborators since our inception in 1996. We wish to continue providing valuable resources in a way that strengthens collaboration and also allows us to benefit from the combination of resources. Please do not hesitate to email [ADC@northwestern.edu](mailto:ADC@northwestern.edu) if you have any questions. The Mesulam Center looks forward to working with you.

Sincerely,

Marsel Mesulam, MD; Center Director  
Bob Vassar, PhD; P30 ADC Director  
John Disterhoft, PhD; Associate Director  
Margaret Flanagan, MD; Neuropathology Core Leader  
Changiz Geula, PhD; Research Education Component Leader  
Darby Morhardt, PhD; Outreach and Recruitment Core Leader  
Hui Zhang, PhD; Biostatistics Core Leader  
Emily Rogalski, PhD; Neuroimaging Core Leader  
Firas Wehbe, PhD, MD; Data Management Core Leader  
Sandra Weintraub, PhD; Associate Director and Clinical Core Leader  
Tamar Gefen, PhD; Assistant Clinical Core Leader

I have read and agree to the above collaboration requirements.

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SIGNATURE OF PI:

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TODAY'S DATE

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**COLLABORATOR INFORMATION**

Principal Investigator (PI):

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PI Phone Number:

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PI Email:

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Primary Contact for Study (if different from PI):

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Study Contact Phone Number (if different from PI):

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Primary Study Contact email:

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Name of Institution and Department:

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Have you previously collaborated with the Mesulam Center for a different study?

- Yes  
 No

Mesulam Center Collaborator Name:

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(A faculty member at the Mesulam Center must be designated to assist you with your project. If you have not yet identified a Mesulam Center collaborator, write "TBD" and one will be assigned to you based upon your research question.)

If applicable, please list any other investigators and institutions affiliated with your project:

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(Write "none" if this does not apply)

OPTIONAL: Please tell us how you learned about our collaborative research opportunities?

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**STUDY INFORMATION**

Study Title:

\_\_\_\_\_

Briefly describe your project's methods, aims and hypothesis:

\_\_\_\_\_

Indicate project start date:

\_\_\_\_\_

Indicate project end date:

\_\_\_\_\_

Which of our resources do you need?

PLEASE NOTE: Due to the current COVID-19 outbreak, all collaborative applications requesting biospecimens, such as brain tissue or blood samples, will be reviewed, but may not be approved or may be approved with limitations.

- Human participants for my project (data are available for participants)
- This project solely requires data (e.g. diagnosis, neuropsychological testing, imaging data)
- Brain tissue/other tissue (e.g. blood, buffy coat, DNA) (clinical data are available on participants)

Indicate what type(s) of data you need (contact information will be provided for human participant referrals):

- None
- Participant and/or caregiver demographics
- Participant health history/family history
- Neuropsychological test scores
- Neurological examination data
- Clinical diagnosis and cognitive status
- Genetics and biomarkers
- Neuropathology data
- Imaging data
- ((Once your collaboration has been approved, you will be invited to provide more specific data needs))

**FUNDING AND IRB INFORMATION**

Has this study been approved by the IRB?

- Yes  
 No  
 Pending  
 Exempt

PLEASE UPLOAD:

- 1) IRB Approval letter (required for all human participant referrals)  
 OR  
 2) Notice of IRB exemption (see below)  
 OR  
 3) Signed MTA agreement (for Industry partners or commercial use). If you have not yet received this, please send as soon as possible.

**EXEMPT REVIEW**

The HHS and FDA regulations include categories of research which are exempt from the regulations. Although the category is called "exempt," at Northwestern University the determination of exemption must be made by the IRB office. Exempt projects are different from Expedited or Full Board Review in that they are not assigned an expiration date, do not have to undergo continuing review, and are able to undergo alterations without IRB approval.

If you believe that your study qualifies for exemption, complete the "New Study" application in eIRB plus. Be sure to select "Exempt" review and choose the exempt category that is applicable to your study.  
<https://irb.northwestern.edu/>

Note: All six exempt categories apply to research involving minors and pregnant women and fetuses. Exempt Category 2 does provide some limitations as to what activities can be conducted in minors. Prisoners may not be studied under research that would otherwise qualify for exemption.

[Attachment: "HRP-312 - WORKSHEET - Exemption Determination.docx"]

What is the project's IRB number (if through Northwestern IRB)? \_\_\_\_\_

Please upload a copy of the consent here, if the document is available. Before data is shared, the consent form must be IRB approved and include HIPPA language.

Is this study likely to lead to publications within two years?

- Yes  
 No

Is this a funded study?

- Yes  
 No  
 Funding Pending

Indicate funding types:

- Federal  
 State  
 Private foundation  
 Institutional (i.e., PI funds, gifts, etc.)  
 Industry

Please list funding agencies: \_\_\_\_\_

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Grant/Funding ID(s):

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Grant/Funding TOTAL:

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**RECRUITMENT OF HUMAN PARTICIPANTS**

Estimated number of participants needed for study:

\_\_\_\_\_

Is more than one (1) study visit required for participation in your study?

- Yes  
 No

Describe the number of visits required:

\_\_\_\_\_

Describe the frequency of study visits:

\_\_\_\_\_  
(e.g. one visit a week; one visit a month; one single visit, etc))

Time spent at each study visit:

\_\_\_\_\_

Will participants be compensated?

- Yes  
 No

Amount of compensation for participation:

\_\_\_\_\_

Amount of compensation for transportation:

\_\_\_\_\_

Please list study inclusion criteria:

\_\_\_\_\_  
(i.e. age 65-80 years old, right handed, diagnosis of Alzheimer's Disease, etc.)

If applicable, please list study exclusion criteria:

\_\_\_\_\_  
(i.e. MRI unsafe, other neurological disorders, etc))

Please list all neuropsychological, psychological, and psychosocial measures captured through your protocol (e.g., MMSE, GDS, Digit Span, etc):

\_\_\_\_\_

Is this a clinical drug trial?

- Yes  
 No

If this is a clinical drug trial, then select all that apply:

- Related to Mesulam Center multi-center consortium arrangements  
 Of interest to the NU Drug Discovery Program  
 Substance not currently available in the Chicagoland area  
 Novel application of existing drugs (investigator initiated)

When will you be ready to start recruitment?

\_\_\_\_\_  
(e.g. July 2016, 07/01/2016, etc))

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When do you anticipate recruitment will end?

\_\_\_\_\_  
(e.g. December 2016, 12/01/2016, etc))

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Tissue needed and amount:

\_\_\_\_\_

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Indicate one (if requesting brain tissue):

- Paraformaldehyde-fixed  
 Frozen

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Number of samples needed:

\_\_\_\_\_

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**PRINCIPAL INVESTIGATOR - PLEASE READ AND SIGN THE FOLLOWING STATEMENT:**

I understand that human tissues may harbor disease-causing pathogens (e.g. viral hepatitis, HIV) that may remain undetected even after routine pathological evaluation, and that all human tissues must therefore be considered biohazardous and potentially dangerous. As Principal Investigator on this project, I acknowledge full responsibility to train any of my laboratory staff who might be exposed to this tissue in its proper handling, use, and disposal, and will provide documentation of such training to the Mesulam Center upon request. Further, I will not transfer tissue provided to me through the Mesulam Center to other investigators, and I will not use the tissue for any additional purposes or study, without the express permission for the Mesulam Center after completion of another Tissue Request Form. I will assume responsibility for any special shipping charges incurred in providing these specimens (e.g., Federal Express). I agree to complete annual requests for progress.

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Collaborator Status:

- Pending approval  
 Active (using resources/recruiting)  
 Active (analysis/closed to recruitment)  
 Inactive  
 Completed  
 Denied  
 Withdrawn  
 On hold  
 Samples provided (NP only)

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Date of Status Update:

\_\_\_\_\_

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Approval Letter

(if applicable)