Mesulam Center Resource Sharing and Tracking Form

POLICY FOR AUTHORSHIP, ACKNOWLEDGEMENT, AND RESOURCE SHARING ON RESEARCH 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 if you have any questions. The Mesulam Center looks forward to working with you.

Sincerely,

Bob Vassar, PhD; Mesulam Center Director and P30 ADRC Director

Sandra Weintraub, PhD; P30 ADRC Associate Director and Clinical Core Co-Leader

John Disterhoft, PhD; P30 ADRC Associate Director

Tamar Gefen, PhD; Clinical Core Co-Leader

Rudolph Castellani, MD; Neuropathology Core Leader

Changiz Geula, PhD; Research Education Component Core Leader

Darby Morhardt, PhD; Outreach, Recruitment, and Engagement Core Leader

Hui Zhang, PhD; Data Core Co-Leader

Marsel Mesulam, MD; Founding Director Emeritus

☐ I have read and agree to the above requirements.

Signature Label

[sig_label]

_____

Printed Name Label

_____

[sig_name_label]

_____

Date of Signature:

_____

REQUESTING RESEARCHER INFORMATION

Principal Investigator (PI):

_____

PI Phone Number:

_____

PI Email:

_____

Is the PI also the primary contact?

◯ Yes
◯ No

Primary Contact for Resource Sharing:

_____

Primary Contact Phone Number:

_____

Primary Contact email:

_____

Name of Institution and Department:

_____

Please list any other investigators and institutions affiliated with your project:

_____
(Write "none" if this does not apply)

MESULAM CENTER RESOURCE SHARING INFORMATION

Mesulam Center Collaborator Name:

_____

(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.)

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

_____

Have you received resources from the Mesulam Center for a different study?

- ☐ Yes
- ☐ No

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))

What Mesulam Center study or studies will the data for this project come from?

- ☐ ADRC
- ☐ PPA
- ☐ SuperAging
- ☐ Clincal Trials
- ☐ Other

If other, specify:

_____

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

Number of visits required:

_____

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))

When do you anticipate recruitment will end?

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

NEUROPATHOLOGY RESOURCE REQUEST

Tissue needed and amount:

_____

Indicate one (if requesting brain tissue):

◯ Paraformaldehyde-fixed
◯ Frozen

Number of samples needed:

_____

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.

_____

IRB INFORMATION

Has this study ([study_title]) been approved by the IRB?

- ◯ Yes
- ◯ No
- ◯ Pending
- ◯ Exempt
- ◯ Not Applicable

If 'no' or 'not applicable', explain below:

_____

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?

_____

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.

PUBLICATION AND FUNDING

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:	_____
Grant/Funding ID(s):	_____
Grant/Funding TOTAL:	_____

Based on the study or studies that are affiliated with this project, the below PIs must approve of this project. They will each individually receive an email to review the project and sign off.

skip the signature section for internal projects?

☐ Sandy
☐ Tamar
☐ Changiz
☐ Rudy
☐ Bob
☐ Darby