Collaborative Application Form

Please complete the survey below regarding requested data from the Northwestern Alzheimer's Disease Center.

Thank you!

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

The work that goes into establishing a research-quality diagnosis, and maintaining a resource such as ours, is considerable. The following is our policy regarding collaboration and access to our resources:

1. 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.

2. The Northwestern Alzheimer's Disease Center must be acknowledged in all publications, abstracts and presentations as follows:
"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 Northwestern Alzheimer's Disease Center and its participants."

3. An annual report will be requested in the beginning of each year, including a list of all abstracts and publications that have emanated from the use of our participants, data or samples.

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.).

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 CNADC looks forward to working with you.

Sincerely,

Marsel Mesulam, MD; Center Director
Bob Vassar, PhD; ADC Director
John Disterhoft, PhD; Associate Director
Eileen Bigio, MD; Neuropathology Core Leader
Changiz Geula, PhD; Research Education Component Leader
Darby Morhardt, PhD; Outreach and Recruitment Core Leader
Fred Rademaker, PhD; Biostatistics Core Leader
Emily Rogalski, PhD; Neuroimaging Core Leader
Firas Wehbe, PhD, MD; Data Management Core Leader
Sandra Weintraub, PhD; Clinical Core Leader

☐ I have read and agree to the above collaboration requirments

SIGNATURE OF PI:

_____

COLLABORATOR INFORMATION

Have you previously collaborated with with the Mesulam CNADC for a different study?
☐ Yes
☐ No

Principal Investigator: _____

Collaborator Status:
◯ Pending approval
◯ Active (using resources/recruiting)
◯ Active (analysis/closed to recruitment)
◯ Inactive
◯ Completed
◯ Denied
◯ Withdrawn
◯ On hold

Date of Status Update: _____

PI Phone Number: _____

PI Email: _____

Primary Contact for Study (if different from PI): _____

Study Contact Phone Number (if different from PI): _____

Primary Study Contact email: _____

Name of Institution (if not Northwestern): _____

Mesulam CNADC Collaborator Name: _____
(A faculty member at the CNADC must be designated to assist you with your project. If you have not yet identified a CNADC 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:
_____
(Write "none" if this does not apply)

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

STUDY INFORMATION

Study Title: _____

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

_____

Which of our resources do you need?

- ◯ Human participants for my project (data are available for referred 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)

RECRUITMENT OF LIVE SUBJECTS

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 subjects be provided compensation?
◯ 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 CNADC 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))

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 NADC upon request. Further, I will not transfer tissue provided to me through the NADC to other investigators, and I will not use the tissue for any additional purposes or study, without the express permission for the NADC 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.

_____

PLEASE SEND:

1) IRB Approval letter (required for all human subjects 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"]

CLINICAL CORE DATA

Indicate what type(s) of data you will need, if applicable (If you've also requested human participants for your study, contact information will be provided to you):

- ☐ 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

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

_____

Proof of exemption or a copy of the IRB Consent form and approval letter (must include HIPAA language) will be required before data are shared. Please upload here if the documentation is available at time of this application:

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:

_____

Indicate project start date:

_____

Indicate project end date:

_____

Grant/Funding ID(s):

_____

Grant/Funding TOTAL:

_____