

## Guidelines & Policies for Investigators Requesting ADRC Resources

All requests for the use of ADRC resources (data, tissue, participants, services) must be approved by the Knight ADRC Leadership Committee. Confirm meeting dates with Marissa Streitz, MSW, Project Manager (314-286-2433; [marissa.streitz@wustl.edu](mailto:marissa.streitz@wustl.edu))

### SUGGESTED TIMELINE

(For Tissue and Participant Requests)

\*\*\*Submit your request according to this timeline or as early as possible. Sooner is always better!!!\*\*\*

- 1) Four (4) weeks prior to submitting your request:
  - (1) Contact Marissa Streitz regarding your request
  - (2) Consult with appropriate Core Leader or Leaders
- 2) *Submit your request by the 15<sup>th</sup> of even-numbered months* (Feb, April, June, Aug, Oct, Dec) to be considered at the committee meeting in odd numbered months.
- 3) Be prepared to submit the following items:
  - (1) Webform at <http://alzheimer.wustl.edu/Research/ResourceRequest.htm>
  - (2) Research description (max. 3 pages) in electronic form. \*See section I.A. for timetable and section I.C. for review procedures

**NOTE:** Data Requests are approved on a rolling basis

### IMPORTANT POINTS

- **Use of ADRC Human Participants or their data** – See section II.A and II.B. for detailed procedural requirements and contacts.
- **Tissue Requests:** Whether banked in the ADRC Neuropathology, Genetics and High Throughput -Omics, Fluid Biomarker, or Biomarker Cores or in another laboratory, these materials (tissue, fluids, etc.) remain under the authority of the Leadership Committee. Questions regarding tissue requests can be directed to the Neuropathology Lab Manager, Ms. Erin Franklin, MS, 314-362-8079, [efranklin@wustl.edu](mailto:efranklin@wustl.edu) or the Neuropathology Core Leader, Dr. Richard Perrin, MD, PhD 314-362-9130, [rperrin@wustl.edu](mailto:rperrin@wustl.edu).
- **Neuroimaging Requests:** The ADRC maintains a database of previously obtained scans that are potentially available to investigators. For questions, please contact the ADRC Neuroimaging Core, Dr. Tammie Benzinger, [benzinger@wustl.edu](mailto:benzinger@wustl.edu). See section IV. for more details.
- **Grant Applications** – If you are submitting a grant proposal that will use ADRC resources, you must submit a letter of intent to the Executive Director Krista Moulder, PhD ([moulderk@wustl.edu](mailto:moulderk@wustl.edu)) **NO LESS THAN 30 DAYS PRIOR TO THE GRANT APPLICATION** deadline. See VII. for more details.

## Guidelines and Policies for Investigators Requesting ADRC Resources

The ADRC encourages and facilitates research and publications by current and new investigators. The ADRC Administration Core is eager to help generate successful proposals, secure funding, and complete and publish study results. **All requests for the use of ADRC resources must be approved by the ADRC Leadership Committee.** If you are in the planning stages of a grant application, pay particular attention to section VII.

**ADRC Leadership Committee Meeting Schedule:** The ADRC Leadership Committee meets the second Monday of January, March, May, July, September, and November each year. The schedule is subject to change; please check with the Knight ADRC Project Manager, Marissa Streitz (314-286-2433; [marissa.streitz@wustl.edu](mailto:marissa.streitz@wustl.edu)) to confirm dates. If your request involves tissue or body fluid (see III. below) or neuroimaging data (see IV. below), then it should be submitted to the ADRC for preliminary review by the respective committees (Tissue or Neuroimaging) **prior** to the Leadership Committee Meeting (see due dates in I.A. below.)

### I. Requesting use of ADRC resources (participants, data, tissue)

**A. Due dates and timetable:** Please consider the following timetable when planning your proposal.

- (1) Two (2) months prior to submission of your request to Leadership Committee: Consult with appropriate Core Leaders (See I.B. below).
- (2) Four (4) weeks prior to submitting **grant** application to outside agency: Submit Letter of Intent to the Executive Director (see paragraph VII. below)
- (3) Two (2) weeks prior to the relevant committee meeting (Biospecimens or Leadership), submit web form and research rationale.

### B. Discussion with and use of Cores prior to submitting requests

- (1) Prior to submitting any application making use of ADRC resources, it is **CRITICAL** that you consult appropriate Core Leaders. Failure to do so could delay approval of your request. If you have any questions on which Core is appropriate, contact Marissa Streitz.

Core	Core Leader	Core Leader Contact
Clinical	Dr. John C. Morris	<a href="mailto:jcmorris@wustl.edu">jcmorris@wustl.edu</a>
Cognitive Assessment Unit	Dr. Jason Hassenstab	<a href="mailto:hassenstabj@wustl.edu">hassenstabj@wustl.edu</a>
Fluid Biomarker	Dr. Suzanne Schindler, Dr. Anne Fagan	<a href="mailto:schindler.s.e@wustl.edu">schindler.s.e@wustl.edu</a> , <a href="mailto:fagana@wustl.edu">fagana@wustl.edu</a>
Neuropathology	Dr. Richard Perrin	<a href="mailto:rperrin@wustl.edu">rperrin@wustl.edu</a>

Biostatistics	Dr. Chengjie Xiong	<a href="mailto:chengjie@wustl.edu">chengjie@wustl.edu</a> (can be substantial help regarding design, power estimations, and analyses; may require budget)
Imaging	Dr. Tammie Benzinger	<a href="mailto:benzingert@wustl.edu">benzingert@wustl.edu</a>
Genetics and High Throughput -Omics	Dr. Carlos Cruchaga, Dr. Oscar Harari	<a href="mailto:cruchagac@wustl.edu">cruchagac@wustl.edu</a> , <a href="mailto:harario@wustl.edu">harario@wustl.edu</a>
Biomarker	Dr. Celeste Karch	<a href="mailto:karchc@wustl.edu">karchc@wustl.edu</a>

### C. ADRC Leadership Committee Review

- (1) Investigators who propose use of ADRC resources (including participants, tissue samples, Core resources, etc.) should submit a brief research rationale (purpose, background and preliminary findings, methods, analytical plan, and list of data variables) electronically to the ADRC Leadership Committee for review. In addition, specific web forms appropriate to the resource (participant, data, tissue) can be found on our website. Although this review and approval need not precede submission of a grant application to an outside agency (See *VII below regarding notifying us in advance of submission to a grant agency*), it must precede initiation of the project. Proposals and questions should be addressed to Marissa Streitz.
- (2) Student investigators (including postdoctoral and medical fellows) must include a letter of support from a faculty advisor who has reviewed the proposal and is responsible for supervising the student's research.
- (3) ADRC Leadership Committee approvals expire 5 years from date of approval. If you are requesting additional data/tissue/participants after your original request approval expires, you must submit a new request.

## II. Procedures Required by the ADRC

### A. Human Studies approvals

- (1) Studies using human participants from the ADRC, their tissue or data derived from such participants, **must** obtain Human Research Protection Office (HRPO) approval from the Washington University Medical School HRPO. (Forms for protocol submission can be obtained from the Washington University School of Medicine Human Research Protection Office website). HRPO will not review the application until the ADRC administration has signed off on the proposal/consent form; therefore, please be certain to submit this proposal early enough for ADRC review.
- (2) HRPO approval is not required for submitting your proposal to us for review, however, you must provide the ADRC office a copy of your WUMS Human or Animal Studies protocol and consent form approval **prior** to initiating your

study. Multi-year studies should forward copies of renewed approval annually to the ADRC office. **FAILURE TO PROVIDE APPROVALS TO THE ADRC OFFICE WILL DELAY YOUR ACCESS TO ADRC RESOURCES.**

- (3) 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.").
- (4) If your request involves archival data or tissue, approval or exemption from the HRPO is still required (e.g., analyses of computerized images or re-analysis of previously collected data to answer a new question).
- (5) If any clinical or genetic information is to accompany autopsy tissue, HRPO approval may be required. Please check with the Human Research Protection Office.

#### **B. Human studies rules regarding use of participant names**

- (1) 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, we recommend you use the participant's date of birth, but since dates are a HIPAA identifier, these data must be secured. Any communication (with the ADRC or anyone else) should use participant ID numbers, **never** names.
- (2) All investigators must abide by the Human Research Protection Office guidelines regarding the securing of participant names. In the Human Studies application, indicate how you will preserve confidentiality; your approval is dependent on this.
- (3) **Investigator orientation to use of ADRC participants** – Before any testing with ADRC participants can begin, the investigator and any research assistant who may be in contact with participants will receive an orientation to procedures for contact and interaction with participants. This orientation includes how they will receive participant information, the "dos and don'ts" of scheduling and testing ADRC participants, and reporting weekly schedules, etc. To schedule this orientation, please contact Becky Fierberg, [rebecca.fierberg@wustl.edu](mailto:rebecca.fierberg@wustl.edu), 314-286-2686.
- (4) **Animal studies approvals** - Studies using animals in conjunction or association with ADRC investigations must obtain approval from the Animal Studies Committee of the Washington University Medical School. A copy of the approval must be sent to the ADRC.

#### **C. Requests for data**

- (1) Requests for data sets for secondary analysis require review by the ADRC. Please complete the ADRC Data Only request form and provide a research rationale of your project. See section I.C.
- (2) Requests for research participant data pursuant to an approved ADRC resource request, including summary statistics on our participant sample and individual

participant details, must be made ONLY to the Biostatistics Core Data Manager (Betsy Grant, PhD, 314-362-3612). Other personnel do not have access to these data. When requesting data from Dr. Grant, please provide your ADRC resource request number (e.g., D2225).

#### **D. Data Sharing**

- (1) Data from ADRC research Projects "belong" to the individual Project Leaders, but the principle of data sharing is endorsed. Such sharing requires mutual trust and cooperation.
- (2) Data from the ADRC Cores should be easily available to all ADRC investigators. When data from a Core are to be used by an investigator not in that Core, the Core Leader must give approval, the contribution of the Core should be acknowledged in resulting publications, and co-authorship from the Core should be considered when appropriate by reason of intellectual contribution. Discuss concerns or ambiguous situations with the ADRC Director, John C. Morris, MD ([jcmorris@wustl.edu](mailto:jcmorris@wustl.edu)).

#### **E. Data Retention, Archiving, and Access**

- (1) Archiving of data from research Projects and Cores in the ADRC is the responsibility of the Biostatistics Core. The nature of the data to be included in the archive will be determined for each Project individually after discussion between the investigator and the Biostatistics Core Leader.
- (2) Data in the archive must have adequate documentation from the original investigator or Core Leader. In addition to the definition of measures, documentation should include, but is not limited to, such information as to how missing data are handled, nature and date of changes made in measurement procedures, special hardware or software requirements for use of the data.
- (3) Data and tissue are archived indefinitely. A research participant may withdraw permission to use tissue or data per the HRPO policies.
- (4) Problems with archived data should be publicized so that later users of the same data can be alerted.

### **III. Requests for Use of Biological Materials**

- A. AUTHORITY--** These materials (tissue, fluids, etc.) remain under the authority of the ADRC Leadership Committee who must approve their usage with input from the Biospecimens Committee by any investigator (including Cores) who wishes to use the material, whether the samples are banked in the Core or in another laboratory. For any questions regarding tissue requests, please contact the Neuropathology Core Leader, Dr. Richard Perrin, MD, PhD 314-362-9130, [rperrin@wustl.edu](mailto:rperrin@wustl.edu). **No third-party sharing is permitted without the approval of the ADRC.**

- B. FORM:** Please complete the "Tissue Request" form and provide a research rationale. See section I.C.
- C. Determine if HUMAN STUDIES APPROVAL** is required for use of archival material.
- D. TIME Limitation on requests:** Unless approved for a longer period of time, all requests are "active" for a maximum of 5 years or until the number of approved samples have been provided, whichever comes first.
- E. Tissue archived by the ADRC is held indefinitely.** If a research participant requests removal of tissue or data from the ADRC archive, HRPO policies will be followed.
- F. The following requirements apply to utilization of ADRC resources:**
- (1) Provide a copy of any publication which contains experimental results obtained from the use of the material.
  - (2) Agree to protect the confidentiality of research participants by not attempting to identify them.
  - (3) Acknowledge our Center and Program Project grants in any presentation or publication that may result from this research: P30 AG066444, P01 AG03991, and P01 AG026276.
  - (4) Should funding result from this research now or in the future, please notify the Executive Director ([moulderk@wustl.edu](mailto:moulderk@wustl.edu)) with details so we may report productivity derived from our resources to NIA.
- G. Common obstacles to approval**
- (1) Inadequate background/justification, including absence of a power calculation to justify the number of samples requested.
  - (2) Poor description of sample requested (the "Diagnostic Impression" sheet may help to define our human participant characteristics and descriptors).
  - (3) Failure to include a list of data variables requested. Putting this information in paragraph form will significantly delay the fulfillment of your request and may result in the omission of desired variables.

**Disclaimer:** No screening for infectious agents has been performed on tissues or bodily fluids provided by the Washington University School of Medicine Knight Alzheimer Disease Research Center. The investigator must take appropriate precautions.

#### **IV. Neuroimaging Studies**

- A.** The Knight Alzheimer Research Imaging (KARI) Committee reviews requests for studies involving neuroimaging. For questions regarding the KARI Committee, please contact Dr. Tammie Benzinger, [benzingert@wustl.edu](mailto:benzingert@wustl.edu).

- (1) When recruiting participants for neuroimaging studies, please specify whether remuneration will be provided and at what rate (\$ per hour) and detailed information about the participant's experience (time in scanner, risks and discomforts). Whenever possible, we ask that the scans be archived with the ADRC.
- (2) The ADRC maintains a database of previously obtained scans that are potentially available to investigators.

## V. Reporting and Publishing Results

- A. Participant Description** - Please report that Clinical Dementia Ratings (CDRs) are obtained "from assessments by experienced clinicians trained in the use of the CDR."

[At the time of enrollment in the ADRC, participants with symptomatic Alzheimer type fulfill certain inclusionary criteria; they and control participants also meet exclusionary criteria. (Inclusionary and exclusionary criteria are cited in publications given below). These strict criteria are followed at entry. However, in these longitudinal studies, participants are not attrited because of later development of various exclusionary criteria. Some have developed evidence for depression, stroke or Parkinson disease, as examples. It is incumbent on investigators to work with the Clinical and Biostatistics Cores to specify how "clean" the participant sample must be for their studies. Participants being tested at some period after enrollment may no longer fulfill all the criteria listed in citations below.]

- B. Citations** - When preparing manuscripts for publication, the following references will be useful for **clinical diagnostic criteria, their validation, and for staging criteria**.

- (1) Berg L, McKeel DW Jr, Miller JP, Storandt M, Rubin EH, Morris JC, Baty J, Coats M, Norton J, Goate AM, Price JL, Gearing M, Mirra SS, Saunders AM. Clinicopathologic studies in cognitively healthy aging and Alzheimer's disease: Relation of histologic markers to dementia severity, age, sex, and APOE genotype. *Arch Neurol* 55:326-335, 1998.
- (2) Morris JC: The Clinical Dementia Rating (CDR): Current version and scoring rules. *Neurology* 43:2412-2414,1993.

## VI. Reporting Requirements

- A. Acknowledgement** of the ADRC contribution and listing of our grant numbers (P30 AG066444, P01 AG03991, P01 AG026276) in publications and grant proposals is expected. Such acknowledgments assist in documenting our success in enhancing and supporting research, a major criterion for evaluation in future ADRC grant renewals.
- B. Reporting of submitted publications and abstracts:** For work using ADRC resources, one copy of EVERY MANUSCRIPT (journal or book) OR ABSTRACT SUBMITTED FOR

PUBLICATION with the cover letter to the Editor should be sent to the ADRC Executive Director (moulderk@wustl.edu) at time of submission.

- C. Receipt of final publications and abstracts** - For work using ADRC resources, publications must follow NIH Public Access policies and obtain a PubMed Central ID number. PLEASE SEND AN ELECTRONIC VERSION (pdf) OF THE REPRINT OF EVERY ABSTRACT, JOURNAL ARTICLE, OR BOOK CHAPTER to BE SUBMITTED to the Executive Director, to be held in our ADRC library. These reprints are vital to grant reporting, documenting ADRC productivity, and aiding us in seeking financial support for our investigators.
- D.** When participants are tested, reporting your testing schedule to the Biostatistics Core via their REDCap data entry system is required.
- E.** After 1 year from receipt of sample (data, tissue, etc.) a brief progress report on utilization is required.

## **VII. Planning and Preparation of Grant Applications**

- A.** Approval by the ADRC Leadership Committee need not precede submission of your grant application. However, if you wish us to provide a letter of support from the ADRC to accompany your application stating that the resources you have requested are available, then a stronger support letter stating that your request for ADRC resources has been approved can be generated instead of one stating the resources are available to you should your application be approved.
- B.** Please remember to consult the appropriate Core Leaders when writing your proposal, as they may be able to assist in developing your proposal. They must also evaluate the availability of resources. When a significant number of resources of a Core will be required, investigators should discuss with the Core Leader including financial support for these resources in their proposal.