



## MADC RESOURCE APPLICATION

An important function of the MADC is to support research (in a financial and non-financial capacity). The following application has been established to guide applicants seeking use of the center's resources. Please carefully review and sign the Policy Guidelines for MADC Support on page 5 before submitting your application.

### Who Can Apply for MADC Resource Support?

The MADC is directed through the Department of Neurology at the University of Michigan. One goal of the center is to provide opportunities for research training. It is therefore appropriate for the MADC to provide support for research by trainees, when possible. Appropriate training can occur only with adequate supervision and faculty guidance, and the policy outlined below is developed to meet this requirement. These guidelines provide information on the types of resources that can be made available to investigators at other institutions and in commercial organizations. Clear lines of research responsibility are needed for these groups. Proposals from trainees and investigators outside UM are judged using the same criteria as those from UM faculty: 1) scientific significance, 2) scientific feasibility, 3) resource availability, and 4) safety and appropriateness to mission. In situations of competing interests, priority is given to established MADC investigators, UM investigators, investigators at other Alzheimer's Disease Centers (ADC's), and other investigators, in that order. First priority for MADC resources are MADC research projects and investigators, and MADC pilot projects.

The following individuals can apply for MADC resource support:

1. **Undergraduate and master's levels students** may not submit applications themselves, but we encourage their faculty advisors to submit applications on their behalf. Students can complete applications themselves, but faculty members must sign the applications and provide letters that indicate that they will provide training, supervise conduct of the study and ultimately be responsible for the study.
2. **Doctoral candidates** may submit applications, if the applications include letters of support from their thesis advisors.
3. **Post-doctoral fellows** may submit applications, if the applications include letters of support from their faculty mentors.
4. **Visiting faculty** may submit applications. The applications should indicate their department and the duration of their visiting status.
5. **Faculty from other educational institutions and investigators at research foundations and federal agencies** may submit applications. The MADC Administrator will contact the institution to establish the accuracy of credentials, including Institutional Review Board (IRB) approval, when appropriate. IRB approval at UM is needed if there is a UM investigator involved in the study.
6. **Investigators at for-profit companies** may submit applications. Letters must be provided indicating that the companies approve and assume legal responsibility for the projects. IRB approval at UM is needed if there is an UM investigator involved in the study.

## **How to Apply for MADC Resource Support**

The MADC Executive Committee will review and determine whether the center's support is justifiable based on 1) relevance to MADC aims, 2) whether adequate resources are available or must be supplemented by the investigator, and 3) whether it is work which the MADC finds ethically, legally and scientifically defensible. For research that previously has not been scientifically reviewed, a consideration of scientific worth is also appropriate and thus requires a more extensive exposition of the proposed project. The IRB is primarily responsible for evaluating human use approval, and it is required before subject names and contact information is released. Please submit the following information:

1. A copy of the scientific protocol (e.g. PDF of NIH grant or other sponsored grant; document using NIH -style format. Please visit <http://www.grants.nih.gov/grants/funding/phs398/phs398.html>).

Protocol should include the following:

- a. A statement of specific aims and research goals
  - b. A testable hypothesis
  - c. A plan for statistical analysis
  - d. Sufficient background for the proposal
2. Biographical sketch

### **MADC Consultation**

Consultation with appropriate MADC faculty and staff prior to the application is encouraged. MADC faculty and staff can provide project design consultation, patient referral, patient data and tissue. The MADC research team can assist with patient selection and evaluation issues. MADC Neuropathology faculty can assist with tissue and assay information. Consultation from the MADC Data team can include database information (without personal identifiers) sufficient to determine feasibility (IRB approval is not required for feasibility studies when no research is conducted, pending approval from the MADC Director). An Education specialist is available for consultation on networking opportunities to facilitate community recruitment, e.g. call center referrals and establishing linkages to residential care communities that support MADC-affiliated research. The Education specialist can also assist in coordinating a meeting with the MADC Director and applicant to discuss strategies to enhance recruitment efforts. If ongoing support from MADC staff will be required during the study (e.g. to assist in subject recruitment), the applicant should discuss with the MADC Administrator and Director plans to budget funded effort for MADC personnel into any planned grant submissions.

### **MADC Volunteer Database**

The MADC Volunteer Database includes healthy controls, individuals with Mild Cognitive Impairment and patients with various forms of dementia based on clinical criteria and research consensus. A list of subjects who potentially qualify for consideration for the applied study only can be generated from the MADC Database by the MADC Database Manager. Once approved, the names and addresses of potential subjects are sent to the investigator. The names generated on this list are limited to those who have filled out an MADC affiliated Research Volunteer Form, indicating their interest in learning about current studies from MADC-approved investigators. The Research Volunteer Form, when completed by the patient or his/her care partner, authorizes MADC investigators to review the patient's medical records and to contact him/her regarding study participation. Once a list is generated from the MADC Volunteer Database, investigators are then authorized to contact the potential subjects. We require that all initial contact of subjects occurs via mail. The MADC will provide the investigator a cover letter to include in the subject mailing. Investigators are required to return information to the MADC Database Manager on a monthly basis regarding the status of each subject referred (see page 3).

## **MADC Research Space**

The MADC has dedicated research space available for use by MADC supported/affiliated researchers. Two well- equipped outpatient research rooms can be reserved by study teams for human clinical research protocols. A dedicated specimen refrigerator and -20°F freezer is also available for use by research teams. Study teams must submit all research room requisitions two weeks in advance. All scheduling is done via email with the MADC Research Coordinator. The MADC operates from 8 AM – 5 PM, Monday – Friday. For industry/federally sponsored research protocols please contact the MADC Administrator at (734) 936-8281 or email [arijit@med.umich.edu](mailto:arijit@med.umich.edu) for budget information.

## **Reporting Requirements for Investigators Receiving Support**

1. An annual written progress report should be submitted to the MADC Administrator (e.g. for NIH funded research, please provide a copy of the competing / noncompeting renewal). A final report must be submitted upon completion of the study.
2. For investigators who have been given a list of subjects from the MADC Volunteer Database, the following information, reported on a monthly basis, is required: a) did the subject qualify for your study? If not, please specify the reason (i.e., too old, no caregiver, living in nursing home, etc.); b) did the subject agree to participate? If not, please specify the reason; or c) is the subject currently under evaluation for study appropriateness. Patients who did not qualify for this study may then be referred to investigators from other studies in the priority order assigned.
3. At the conclusion of the study, a 5-10 minute presentation must be given to the MADC Executive Committee.
4. All publications resulting from use of MADC resources must be reported to the MADC Administrator UPON ACCEPTANCE FOR PUBLICATION. A reprint is required for the MADC files.
5. Any grant funds received as a result of the use of MADC Resources must be reported to the MADC Administrator.



## MADC RESOURCE APPLICATION

Please attach a protocol of your study, including Hypothesis, Specific Aims, Research Methods, etc. Application and supporting documents can be sent to Ari Bhaumik at [arijit@med.umich.edu](mailto:arijit@med.umich.edu); fax (734) 764-6444 or 2101 Commonwealth Blvd., Ste. D., Ann Arbor, MI 48105. Inquires can be made at (734) 936-8281.

### APPLICANT INFORMATION

Applicant Name:

Phone:

Institution:

Fax:

Mailing Address:

Email Address:

Title of Application:

Funding Agency:

Funding Application Deadline: \_\_\_ / \_\_\_ / \_\_\_

Grant Number:

Total Direct Costs:

Project Start Date: \_\_\_ / \_\_\_ / \_\_\_

End Date: \_\_\_ / \_\_\_ / \_\_\_

IRB APPROVAL # & Date:

### USE OF MADC RESOURCES

Do you want the MADC to identify subjects? YES  NO

Types of Subjects Needed (age range, clinical diagnosis, exclusions, etc.):

Total Number of Subjects Needed:

Research Space Needed (# visits/duration):

If neuropsychological test data are required (i.e. MMSE, GDS, etc.), please specify:

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MADC Use

Date Received by MADC \_\_\_ / \_\_\_ / \_\_\_

Date Approved \_\_\_ / \_\_\_ / \_\_\_

## **POLICY GUIDELINES FOR MADC SUPPORT**

This policy is based on balancing the mandate to promote research and research training and the need to establish accountability and assure appropriate conduct of research. Please carefully review these requirements and submit a signed copy with your application documents. For questions, please call (734) 936-8281.

### **Administrative Requirements**

1. All applicable IRB approval information must be current and IRB number supplied. Documentation of IRB approval **MUST** be received by the MADC before subject names and contact information is released. IRB approval is not required for feasibility studies when no research is conducted.
2. The MADC decision concerning approval of this application will be based on the ability to support the proposed project, its scientific merit, and relevance. Please provide all supporting documents that you believe would be helpful in the review. Proprietary studies cannot be supported by MADC resources.
3. Priority order includes: MADC faculty and Pilot projects; MADC supported clinical trials; MADC affiliated studies.
4. The applicant agrees that the MADC's Executive Committee and/or Neuropathology Resource leader will monitor compliance with the criteria and standards stated heretofore and others as may be applicable, and have the authority to determine appropriate corrective measures, as needed.

### **Recruitment Requirements**

1. Names of subjects provided via the MADC Volunteer Database are not to be shared with other researchers or for use in any other study. Each separate study requesting the use of MADC Resources will require replication of the application process.
2. Neuropsychological test data provided should only be for the use as originally stated.
3. Initial contact of subjects will occur via mail. The MADC will provide the applicant with a cover-letter indicating approval of your project by the research center.

### **Reporting Requirements**

1. If there is a significant change in the project, such as change in the PI or other key personnel, moving of the project, etc., the MADC should be notified in writing in advance, if possible.
2. Applicant is required to provide a monthly update on the recruitment status of each individual on the subject list. Please contact Sherry Teboe at (734) 764-4433 or [steboe@umich.edu](mailto:steboe@umich.edu) with questions about this reporting requirement.
3. To assist with MADC grant preparation and ensure effective allocation of MADC resources, the applicant will be asked to provide a brief progress report including a list of all publications generated as a result of use of MADC resources. MADC must be acknowledged in publications resulting from the use of MADC resources.

I have reviewed the Policy for MADC Resources Support and agree to abide by the conditions stated therein.

5 Applicant Signature: \_\_\_\_\_ Date: \_\_\_\_ / \_\_\_\_ / \_\_\_\_