Michigan ADRC
Alzheimer's Disease Research Center

MADRC RESOURCE APPLICATION

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

Who Can Apply for MADRC Resource Support?

The MADRC 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 MADRC 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 U-M are judged using the same criteria as those from U-M 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 MADRC investigators, U-M investigators, investigators at other Alzheimer's Disease Research Centers (ADRC's), and other investigators, in that order. First priority for MADRC resources are MADRC research projects and investigators, and MADRC pilot projects.

The following individuals can apply for MADRC 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 MADRC Administrator will contact the institution to establish the accuracy of credentials, including Institutional Review Board (IRB) approval, when appropriate. IRB/sIRB approval/exemption notice at U-M is needed if there is a U-M 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/sIRB approval/exemption at U-M is needed if there is a U-M investigator involved in the study.

How to Apply for MADRC Resource Support

The MADRC Executive Committee will review and determine whether the center's support is justifiable based on 1) relevance to MADRC aims, 2) whether adequate resources are available or must be supplemented by the investigator, and 3) whether it is work which the MADRC 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

MADRC Consultation

Consultation with appropriate MADRC faculty and staff prior to the application is encouraged. MADRC faculty and staff can provide project design consultation, patient referral, patient data and tissue. The MADRC Clinical and Outreach, Recruitment, and Engagement Cores can assist with patient selection and evaluation issues. MADRC Neuropathology/Biomaker faculty can assist with tissue and assay information. Consultation from the MADRC Data Core can include database information (without personal identifiers) sufficient to determine feasibility (IRB approval is not required for feasibility/cohort discovery studies when no research is conducted, pending approval from the MADRC Director). An Outreach, Recruitment, and Engagement (ORE) Core manager 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 MADRC affiliated research. The ORE Core manager can also assist in coordinating a meeting with the MADRC Director and applicant to discuss strategies to enhance recruitment efforts.

If ongoing support from the MADRC staff will be required during the study (e.g. to assist in subject recruitment), the applicant should discuss with the MADRC Research Administrator and Director plans to budget funded effort for MADRC personnel into any planned grant submissions.

MADRC MiNDSet Research Registry

The MADRC MiNDSet Research Registry 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 MADRC MiNDSet Registry by the Data Core 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 MADRC affiliated

Research Volunteer Form, indicating their interest in learning about current studies from MADRC approved investigators. The Research Volunteer Form, when completed by the patient or his/her care partner, authorizes MADRC investigators to review the patient's medical records and to contact him/her regarding study participation. Once a list is generated from the MADRC Registry, investigators are then authorized to contact the potential subjects. We require that all initial contact of subjects occurs via mail. The MADRC will provide the investigator a cover letter to include in the subject mailing. Investigators are required to return information to the MADRC Recruitment Coordinator on a monthly basis regarding the status of each subject referred (see below).

MADRC Research Space

The MADRC has dedicated research space available for use by MADRC supported/affiliated researchers. Four research examination rooms for physical/neurological exams and two interview rooms can be reserved by study teams for human clinical research protocols. A research laboratory/dedicated blood draw station 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 MADRC Research Coordinator. The MADRC operates from 8 AM – 5 PM, Monday – Friday. For industry/federally sponsored research protocols please contact the MADRC Administrator Arijit Bhaumik at (734) 936-8281 or email: arijit@med.umich.edu for budget/facilities information.

Reporting Requirements for Investigators Receiving Support

1. An annual written progress report should be submitted to the MADRC 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 MADRC MiNDSet Registry, the following information, reported on a monthly basis, is required: a) did the subject qualify for your study? If not, please specify the reason (e.g.., too young or old, no caregiver or study partner, 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 MADRC Executive Committee for all MADRC funded pilots.

4. All publications resulting from use of MADRC resources must be reported to the MADRC Administrator UPON ACCEPTANCE FOR PUBLICATION. A reprint is required for the MADRC files.

5. Acknowledgment and Logos

    - Please remember to acknowledge partial support from NIH/NIA grant P30AG072931 in your publications, presentations, web-sites, posters, and other dissemination efforts that are related to MADRC research, development and training activities and also include an approved MADRC logo.

Text must read:

This <project/study (choose one)> was partially supported by the NIH/NIA funded Michigan Alzheimer's Disease Research Center (P30AG072931).

Logos:
For approved MADRC logos to use in posters and presentations, please contact:

Renee Gadwa, MADRC Outreach, Recruitment, and Engagement Core Program Manager
email: rgadwa@med.umich.edu

6. Any grant funds received as a result of the use of MADRC Resources must be reported to the MADRC Administrators Arijit Bhaumik and Nancy Laracey.

MADRC RESOURCE APPLICATION

Please attach a protocol of your study, including Hypothesis, Specific Aims, Research Methods, IRB/sIRB Approval notification, IRB/sIRB approved Informed Consent document, and study brochures. Application and supporting documents can be sent to Arijit Bhaumik at 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 MADRC RESOURCES

Do you want the MADRC 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:

MADRC Use
Date Received: _____/_____/_____ Date Approved ____/____/____

POLICY GUIDELINES FOR MADRC 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 contact the MADRC Research Administrator Arijit Bhaumik at (734) 936-8281 or email arijit@med.umich.edu.

Administrative Requirements

1. All applicable IRB approval information must be current and IRB number supplied. Documentation of IRB approval MUST be received by the MADRC before subject names and contact information is released. IRB approval is not required for feasibility studies when no research is conducted.

2. The MADRC 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 MADRC resources.

3. Priority order includes: MADRC faculty and Pilot projects; MADRC supported clinical trials; MADRC affiliated studies.

4. The applicant agrees that the MADRC'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 MADRC MiNDSet Registry are not to be shared with other researchers or for use in any other study. Each separate study requesting the use of MADRC 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 MADRC 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 MADRC 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 Arijit Bhaumik (734) 936-8281 or arijit@med.umich.edu with questions about this reporting requirement.

3. To assist with MADRC grant preparation and ensure effective allocation of MADRC 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 MADRC resources. MADRC must be acknowledged in publications resulting from the use of MADRC resources.

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

Date____/____/____