



APPLICATION FOR CORE RESOURCES

An important function of the MADRC is to support research not funded as part of our Center grant. The following application has been established to guide applicants seeking use of Core resources. Please carefully review and sign the Policy Guidelines for MADRC Support on page 5 before submitting your application.

Who Can Apply for MADRC Core Support

The MADRC is directed through National Institute on Aging (NIA) guidelines to provide opportunities for research training. It is therefore appropriate to provide Core support for research by trainees, when possible. Appropriate training can occur only with adequate supervision and faculty guidance. The provisions of this policy are developed to meet this requirement. NIA guidelines also make clear that Core resources should 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 value, 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, UM investigators, investigators at other Alzheimer's Disease Centers (ADC's), and other investigators, in that order. First priority for Core resources are MADRC research projects and Cores, MADRC pilot projects, National Alzheimer's Coordinating Center (NACC) data submissions, NACC projects, and NIA data and information requests and requirements. The following individuals can apply for MADRC Core 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 be ultimately 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 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 MADRC Core Support

The intent of Executive Committee review is to determine whether Core support is justifiable based upon 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 is required (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 Core Support Consultation

Consultation with appropriate Core Directors prior to the application is suggested. MADRC Core Directors provide project design consultation, patient referral, patient data and tissue. The Clinical Core Director can assist with patient selection and evaluation issues. Neuropathology Core Director can assist with tissue and assay information. Consultation from the Data Core 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 respective Core Director). The Education Core is an available resource for consultation on networking opportunities to facilitate community recruitment, e.g. establishing linkages to residential care communities that support MADRC-affiliated research. The Education Core Coordinator can also assist in coordinating a meeting with the Clinical Core team, which includes the Clinical Core Director and MADRC Study Coordinators, to discuss strategies to enhance recruitment efforts.

MADRC Volunteer Database

A list of subjects who potentially qualify for consideration for the applied study only can be generated from the MADRC Volunteer Database by Data Core staff. Once approved, the names and addresses of potential subjects are sent to the investigator. The names generated on this list are limited to individuals in the longitudinal cohort of the MADRC and those who have signed an MADRC affiliated Research Preference Form, indicating their interest in learning about current studies from MADRC-approved investigators. The Research Preference Form, when signed 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 Volunteer Database, investigators are then authorized to contact the potential subjects. It is required that all initial contact of subjects occur via mail. The MADRC will provide the investigator a coverletter to include in the subject mailing. Investigators are required to return information to the MADRC Database Coordinator on a monthly basis regarding the status of each subject referred (see page 3).

The MADRC Volunteer Database includes healthy controls, individuals with Mild Cognitive Impairment and patients with a dementia diagnosis based on clinical criteria and research consensus.

Reporting Requirements for Investigators Receiving Core 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 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 MADRC Executive Committee.
4. The grant P50 - AG08671 must be cited in any publications resulting from the study.
5. All publications resulting from use of MADRC Core resources must be reported to the MADRC Administrator UPON ACCEPTANCE FOR PUBLICATION. A reprint is required for the MADRC files.
6. Any grant funds received as a result of the use of MADRC Core Resources must be reported to the MADRC Administrator.

Approved by the MADRC executive committee on 10/26/2009.



MICHIGAN ALZHEIMER'S DISEASE RESEARCH CENTER CLINICAL CORE RESOURCE APPLICATION

Please attach a protocol of your study, including Hypothesis, Specific Aims, Research Methods, etc. Application and supporting documents can be sent to Courtney McDonald at ckenned@med.umich.edu; fax (734) 764- 6444 or 2101 Commonwealth Blvd., Ste. D., Ann Arbor, MI 48105. Inquires can be made at (734) 615-8462.

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 CLINICAL CORE RESOURCES

Do you want the MADRC to identify subjects? YES ___ NO ___

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

Total Number of Subjects Needed:

If neuropsychological test data are required or testing is needed, please specify:

MADRC Use

Date Received by MADRC ___ / ___ / ___

Date Approved ___ / ___ / ___

POLICY GUIDELINES FOR MADRC CORE 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.

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 Core and Pilot projects; MADRC supported clinical trials; MADRC affiliated studies.
4. The applicant agrees that the MADRC's Executive Committee, Clinical Core and Administrative Core 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 Volunteer Database are not to be shared with other researchers or for use in any other study. Each separate study requesting the use of MADRC Clinical Core Resources will require replication of the application process.
2. Neuropsychological test data provided should be only for 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 Sherry Teboe at (734) 764-4433 with questions about this reporting requirement.
3. In order to assist with MADRC renewal preparation, the applicant is responsible for providing a brief progress report including a list of all publications generated as a result of use of MADRC resources. MADRC **grant P50—AG08671** must be acknowledged in publications resulting from the use of MADRC resources.

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

Applicant Signature: _____

Date: ___ / ___ / ___