

Policy for Michigan Alzheimer's Disease Research Center (MADRC) Core Support

[Applications and supporting documents should be emailed to Dr. Sid Gilman, Director, MADRC (sgilman@umich.edu)]

An important function of the MADRC is to support research not funded as part of our Center grant. Institutions must demonstrate considerable peer-reviewed AD research in order to qualify for an ADC, and the extent of Core funding is justified in large part on the promotion and support of such institutional research. The following policies have been established to guide applicants seeking use of core resources.

Who Can Apply for MADRC Core Support

This policy is based on balancing the mandate to promote research and research training on the one hand, and the need to establish accountability and assure appropriate conduct of research on the other. 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 these concerns. 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, 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. It is understood that the 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.

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 be providing 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 approval from their thesis advisors.

3. **Post-doctoral fellows** may submit applications, if the applications include letters 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 Core support is provided.

1. Consultation with appropriate Core directors prior to the application is suggested.
2. No specific form for the scientific proposal is required. NIH format is optional.
3. A statement of specific aims and research goals is needed.
4. A testable hypothesis should be stated.
5. Sufficient background needs to be submitted to assure the reviewers that the investigator is prepared to complete the study.
6. A plan for analysis must be provided.

When to Request MADRC Core Support Consultation

MADRC cores provide consultation when feasible, patient referral, patient data and tissue. Consultation and patient referral are most resource intensive.

1. Core directors are encouraged to provide consultation to potential investigators when feasible and are expected to allocate some of their effort to do this and may do so without the approval of the MADRC Executive Committee. Core directors should notify the MADRC Administrator that they are providing consultation and keep a record of the investigator, purpose and length of the consultation for use in reports of grant activity.
2. Consultation can include database information (without personal identifiers) sufficient to determine feasibility (IRB approval is not required for feasibility studies when no research is conducted). (NOTE: Is this worded correctly?)
3. The MADRC Administrator should follow up with the investigator to determine that appropriate support was provided and to monitor outcomes.
4. The Administrator should periodically report consultation activities to the MADRC Executive Committee

Description of Subject Recruitment Procedures

Research subjects can be recruited from the MADRC in two ways:

1. Cognitive Disorders Clinic faculty and staff may ask each patient seen in the Clinic to sign a research preference form after discussing with them the MADRC Longitudinal Study and other studies currently being conducted by investigators with approval to use MADRC core resources. This research preference form, when signed by the patient or his/her study partner, authorizes MADRC investigators to review the patient's medical records and to contact him/her regarding study participation. Each patient signing a research preference form is reviewed at a weekly conference to determine his/her appropriateness for current MADRC-related studies, and patients are assigned to study coordinators in priority order. Study coordinators are then authorized to contact these potential subjects. Coordinators are required to return information to the Database Coordinator on a bi-weekly basis regarding the status of each referred patient: 1) agreed to participate, 2) under evaluation, or 3) inappropriate for the study (including reasons). Patients who do not qualify for this study may then be referred to other study coordinators for other studies in the priority order assigned.

2. A list of subjects who potentially qualify for the study can be generated from the MADRC database by the Data Core staff. Once approved, the names and addresses of potential subjects are sent to the investigator. The investigator must mail information about the study to subjects and provide a pre-paid postcard that they can return if they do not wish to be contacted. The names generated on this list are limited to individuals in the longitudinal cohort of the MADRC (about 220 patients with dementing disorders and 200 normal controls) and those who have signed a statement ("clinic waiver") indicating their interest in learning about current studies from MADRC approved investigators. We have only recently asked patients and families to sign the clinic waiver and so this group currently is very small.

Reporting Requirements for Investigators Receiving Core Support

1. A written progress report should be submitted within six months of receiving core support, and a final report submitted upon completion of the study.
2. For investigators who have been given a list of patients from our database, we need the following information, reported on a monthly basis: a) was the patient interested in your study?; b) did the patient qualify for your study? If they did not qualify, please specify the reason (i.e., too old, no caregiver, living in NH, etc.); c) did the patient agree to participate? If not, please specify the reason.; d) did the patient participate in your study? Please contact Sherry Teboe at (734) 764-4433 with questions about this reporting requirement.
3. At the conclusion of the study, a 5-10 minute presentation must be given to the MADRC Executive Committee.
4. The grant 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 12/04.