Rio Grande Valley Alzheimer´s Disease Resource Center for Minority Aging Research (AD-RCMAR): Partnerships for Progress

RGV AD-RCMAR PILOT RESEARCH STUDY APPLICATION GUIDELINES

This application is a significantly abbreviated and modified version of an NIH application for K-type awards and R21-type awards. Not only is it shorter than either, but it also is a somewhat "hybridized" version for the purposes of this program. The format is designed to standardize the submissions formats (make them comparable so that the reviewers can better appreciate the strengths of all proposals equally without being distracted by formatting differences) and familiarize applicants with basic features of NIH grant applications.

Blank pages, except for main section headers, for the application can be found in the MS Word (.docx) files provided. All file names take the form of "AD-RCMAR_0<x>_<section name identifier>." The number "_0x_" in the file name is meant to indicate the order in which the documents will be assembled in the finished application. The exception is "_XX_." That is a "continuation" page that can be copied and used after the first page in multi-page sections. In those cases, if you would rather use completely blank sheets, feel free to do so.

Applicants should delete placeholder pages and pages that are irrelevant (i.e., N/A) to their proposed study from their final compiled versions.

Format
11 pt. Arial Font throughout.
½ Inch Margins (top, bottom, left, and right: e.g., "Narrow" in MS Word Layout Menu**)**
Please begin each new section on separate page: i.e., do not run sections together.

Elements and Page Limits	Instructions/Format
Face Page (1 page, provided)	Please use the provided page.
Project Summary/Abstract (Maximum 30 lines)	The Project Summary must contain a summary of the proposed activity suitable for dissemination to the public. It should be a self-contained description of the project and should include a statement of objectives and methods to be employed. It should be informative to other persons working in the same or related fields and insofar as possible understandable to a scientifically or technically literate lay reader. This Summary must not include any proprietary/confidential information. The Project Summary is meant to serve as a succinct and accurate description of the proposed work when separated from the application. Again, be certain to state the application's broad, long-term objectives and specific aims, making reference to the relatedness to Alzheimer's disease and/or related dementias (ADRD). Describe very concisely the research design and methods for achieving the stated goals. Avoid describing past accomplishments and the use of the first person in this section.
Budget Justification (1 page maximum)	Provide a succinct justification of the requested budget for the 1-year pilot research project. Provide an estimated amount (in round dollars) plus brief project-oriented budget justification for each item. If applicable, put the following categories in this order:

	PERSONNEL, SUPPLIES, TRAVEL, OTHER RESEARCH EXPENSIVES. Enter "N/A" if none. "EQUIPMENT" may not be included in the budget. Per NIH: Equipment = "Tangible personal property (including information technology systems) having a useful life of more than one year…" And per RCMAR pilot study instructions: "…a per-unit acquisition cost which equals or exceeds $5,000." Please contact Pilot Study Program Coordinator or Project Coordinator for clarification if necessary. All items must be justified in terms of their necessity for the successful completion of the specific aims of the proposed AD-RCMAR pilot research project (Any questions should be addressed to the Pilot Studies Program Coordinator or AD-RCMAR Project Coordinator). Note: provide names, roles/purposes for each entry.
Biosketches or CVs (5 pages maximum each)	Provide a biographical sketch or a current CV for the applicant. Primary mentors should provide a Biosketch and Secondary Mentors may use a NIH Biosketch. A modified blank Biosketch form can be found in the following file ("AD-RCMAR_04b_BIOSKETCH_blank_PAGE"). It can also be found at: https://grants.nih.gov/grants/forms/biosketch.htm Note: Persons using the modified Biosketch provided by the AD-RCMAR should delete the instructions on it before assembling the application.
Specific Aims (1 page maximum)	State precisely the goals of the proposed research and summarize the expected outcome(s) including the impact that the results of the proposed research will exert on the research field(s) involved – i.e., what gap(s) in knowledge would this pilot research study fill or prepare you to fill in future research. Then list succinctly the specific objectives of the research proposed – e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop new technology. Limit to two Specific Aims.
Research Strategy (6 pages maximum)	Organize the Research Strategy in the specified order using the instructions provided below. Start each section with the appropriate section heading – Significance, Innovation, Approach. Cite published experimental details in the Research Strategy section (the full references will be listed under Bibliography and References Cited later in the application). **Number each subsection according to the scheme below: e.g., for the for section (Significance), the header should be "1. Significance," and the first point (below that) should be "1.a." followed by the** text**.** **1. Significance** a. Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses.

	b. Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields. c. Describe how the concepts, methods, technologies, services, or future studies that drive this field will be changed if the proposed aims are achieved. **2. Innovation** a. Explain how the application challenges current research or practice paradigms. b. Describe any novel theoretical concepts, approaches or methodologies, instrumentation or interventions to be developed or used, and any advantage over existing methodologies, instrumentation, or interventions. **3. Approach** a. Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Unless addressed separately elsewhere, include how the data will be collected, analyzed, and interpreted as well as any resource sharing plans as appropriate. b. Identify any potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims. c. Point out any procedures, situations, or materials that may be hazardous to personnel and precautions to be exercised (only if applicable).
Future Plans (1 page maximum)	This section is specific to a RGV AD-RCMAR pilot research study application. Outline a plan for proceeding from a successfully completed pilot study to… 1. Publication of results 2. Preparation and submission of a competitive application for extramural funding for a subsequent study from the National Institutes of Health (noting relevant institutes, programs, funding opportunities). **Note**: This information is factored into the assessment of the likelihood that the proposed research study could lead to a successful application to NIH for an independent investigator-initiated research grant award.
Career Development (1 page maximum)	**1. Candidate's Background** [Briefly] Describe your past scientific history, indicating how the award fits into past and future research career development. If there are consistent themes or issues that have guided previous work, please refer to these here; if your work is changing direction, the reasons for the change should be indicated. **2. Career Goals and Objectives** Describe your short-term and long-term career goals and objectives, and how the career development award is envisioned to enable you to develop and/or expand your research career.

	*If you have not done so elsewhere, you should indicate what training you have already received that will help you successfully complete this study and further enhance your research career development: e.g., data management, epidemiology, study design (including statistics); etc.
AD-RCMAR Participation Statement (1/2 page –1 page, 1-page maximum)	Include a statement that the candidate will commit the proposed and approved time necessary to complete the approved RGV AD-RCMAR pilot research project and participate in other RGV AD-RCMAR-related career development activities necessary to eventually move forward into the/an ADRD/aging-related research workforce. Examples of the latter include Orientation(s) to UTRGV and Grant-Related Federal Processes & Regulations*; certification and seminars in the Responsible Conduct of Biomedical & Social/Behavioral Research**; and Journal Club. *Required by RGV AD-RCMAR. **Required by UTRGV & NIH. The Head of the applicant's academic unit must provide a Letter of Institutional Support indicating what percentage of the applicant's time will be protected (below). **Note: RGV AD-RCMAR Plans will be designed to accommodate each applicant's needs** (i.e., not "one size fits all")**.**
Protection of Human Subjects (1 – 2 pages, 2-page maximum)	Complete using blank continuation pages provided. This section is required for applicants whose project involves human subjects. Do not use this Protection of Human Subjects section to circumvent the page limits of the Research Strategy. This section is highly abbreviated for the purposes of the proposed study. It is only included to be certain that the applicants are aware of the sorts of issues they will have to address in future applications they may submit. In any case, this section would never substitute for a required review of the study by the institution's IRB before it commences. For the purposes of the RGV AD-RCMAR Pilot Research Study, no intervention studies or clinical trials requiring recruitment of participants will be considered this year, so most of the risks that accompany such studies will apply here. Please address the following points with respect to data and biomaterials (regardless the source) from human research subjects. Consider the nature of the data and what protections should be afforded. Are the data anonymous IDs (i.e., ID is replaced by alphanumeric label, with no link to any PII. No one will ever be able to link the data to a specific person)? Are they de-identified (i.e., personal identifiers have been removed from the data, so that you do not know the specific individual, but the investigator or their designee safely maintaining the links between

	the coded ID numbers and the PII, could possibly join the PII and the data)?
	
	Succinctly address the following points in this section.
	1. Risks to Human Subjects Involvement, Characteristics, and Design
	  a. Human Subjects Involvement, Characteristics, and Design
	  b. Study Procedures, Materials, and Potential Risks
	  i. Here, how will you obtain the data? What potential risks are there to the participants (e.g., loss of anonymity, loss of privacy)?
	2. Adequacy of Protection Against Risk
	  a. Did the participants (originally, for example) provide informed consent (i.e., willingly make their data or biomaterials available)? How?
	  b. Protections Against Risk
	  i. How and where are the IDs coded and stored? How safe are they?

Vertebrate Animals (1 page maximum)	Complete using a blank continuation page (provided). This page is required only for applicants whose project will involve vertebrate animals. If not proposing to use vertebrate animals, do not include in your application. If proposing to use (non-human) vertebrate animal research model, succinctly* include the following points. *For the purpose of this RGV AD-RCMAR pilot research study proposal, completion of this section could include bullet points. 1. Provide a succinct description of the proposed use of the animals in the work outlined in the Research Strategy section. Identify the species, strains, ages, sex, and numbers of animals to be used in the proposed work. 2. Succinctly justify the proposed use of animals. 3. Succinctly describe procedures to limit discomfort, distress, pain, and/or injury.
BIBLIOGRAPHY/REFERENCES CITED (No page limit)	Complete using blank pages. Provide a bibliography of any references cited in the Specific Aims and Research Strategy sections. Each reference must include the names of all authors (in the same sequence in which they appear in the publication), the article and journal title, book title, volume number, page numbers, and year of publication. Include only bibliographic citations. Applicants should be especially careful to follow scholarly practices in providing citations for source materials relied upon when preparing any section of the application.
LETTER OF INSTITUTIONAL SUPPORT (1 page maximum)	Letter of Institutional Support from Head of applicant's Academic Unit. This must be a brief, signed institutional letter of support from either your department chair or division chief confirming that you will have a junior-level faculty appointment between

	07/01/2021 and 06/30/2022 and adequate "protected time" during that period to conduct your proposed pilot project. While percentage of "protected time" should be noted, specific dollar amounts should not be provided at this time.
ADDITIONAL LETTER(S) OF SUPPORT FROM COLLABORATORS AND/OR CONSULTANTS (1 page maximum each)	**Not required. Include only if appropriate.** Examples, 1) if you proposed to obtain data or biomaterials from another, non-RGV AD-RCMAR faculty or program or 2) if the proposed study in your application required the contribution(s) of consultant to be completed successfully, letter(s) would be appropriate here.

For clarification of any of the above, please contact the Pilot Studies Program Coordinator, Dr. Michael C. Mahaney (michael.mahaney@utrgv.edu) or the RGV AD-RCMAR Project Coordinator, Ms. Claudia Alaniz (claudia.alaniz01@utrgv.edu).