School of Public Health
BROWN UNIVERSITY

2022 Call for Alzheimer's Disease and Related Dementias Pilot Projects

Purpose. Brown University is issuing a call for applications for pilot projects to generate preliminary study data necessary for investigators to prepare to develop or test interventions for persons living with Alzheimer's Disease and Related Dementias (ADRD) using embedded pragmatic methods. Embedded interventions involve healthcare providers or systems implementing new protocols or interventions.

These pilot projects are funded annually as part of a National Institute on Aging (NIA) Program Project Grant (PPG) that conducts health services research to inform and improve the care of people living with ADRD and/or their families. The PPG's three cores and four projects focus on the effects of national Medicare payment and quality regulation policies on the outcomes experienced by persons with ADRD:

- Project 1 seeks to determine whether ADRD constitutes a disparity in access to high-quality post-acute nursing care and whether alternative payment models that incentivize greater continuity reduce this disparity, resulting in improved outcomes.
- Project 2 seeks to understand how accountable care organizations' approach to care delivery impacts the experience and outcomes of vulnerable older persons with advanced dementia.
- Project 3 evaluates the impact of Medicare Advantage on the outcomes for ADRD patients using home health, skilled nursing, or end-of-life care in a nursing home.
- Project 4 examines the intended and unintended consequences of federal policies designed to reduce the use of antipsychotic drugs on the outcomes experienced by persons with ADRD residing in nursing homes, assisted living communities, and the community.

Awardees may benefit from the mentorship of experienced PPG investigators from institutions across the U.S. and access to the PPG's national data holdings (Attachment A).

Focus. Projects must relate both to ADRD and to preparing to develop or test an intervention for a future embedded pragmatic study, although they may be at an early stage of preparation (e.g., preliminary analyses or stakeholder engagement), not necessarily intervention design or pilot testing. Applicants must describe (1) the relevance of their proposed project to people living with ADRD or their caregivers and (2) how their proposed project will help them to move along the interventional research development continuum towards embedded pragmatic research. They are also encouraged to review the Readiness Assessment for Pragmatic Trials (RAPT) model and consider how a pilot may help them to generate preliminary data or knowledge that strengthens readiness in one or more domains.

Scope. This solicitation will fund up to two 12-month pilot projects, with a budget of up to $40,000 in direct costs. Projects must either be exempt category 4 or not be considered human subjects research. Applicants should review the Brown IRB's decision chart and exemption categories to ensure projects meet this requirement. Applicants invited to submit a full proposal will be required to complete a human subjects research plan to affirm that their project is either exempt category 4 or not be considered human subjects research and to be submitted to NIA. If it is determined this is human subjects research, applicants must complete and submit the Human Subject Study Record: PHS Human Subjects and Clinical Trials Information Form.

Examples of permissible projects include:

- Secondary data analyses using the PPG data holdings or a health system's data

- Qualitative data collection, such as stakeholder engagement
- Quality improvement, such as small-scale pilot testing to refine an intervention
- Program evaluation to generate preliminary data

For example, projects could focus on developing or validating outcome measures for pragmatic evaluation of an intervention; on characterizing a population or problem, in preparation for identifying or designing an intervention; or on partnering with providers to understand a problem or contextual factors related to intervention design or delivery. Applicants may review examples of funded pilot projects on the LTCFocus ADRD Pilot Projects webpage. Use of the PPG's data holdings is not required.

Eligibility. Priority will be given to early career researchers. Applicants must be a faculty member, fellow, or investigator at an academic institution and eligible to receive NIA funding. Co-PIs are permitted.

While use of the PPG's data holdings is not required, applicants who do propose to use the data must either (1) work with a Brown analyst (deducting $15,000 from their budget; see Budget section) or (2) demonstrate that they have programming experience (personally or at their institution) and be affiliated with an institution that has an investigator named on the PPG's data use agreement (i.e., Brown University, Hebrew SeniorLife, University of Michigan, University of Pennsylvania, or Vanderbilt University Medical Center). Applicants not affiliated with one of these institutions are required to work with a Brown analyst. This information must be in the application.

Budget. If not proposing to work with a Brown analyst: up to $40,000 in direct costs, exclusive of indirect costs. Personnel and supply costs are permitted; tuition and equipment costs are prohibited. If proposing to work with a Brown analyst: up to $25,000 in direct costs, exclusive of indirect costs. Up to $15,000 for the Brown analyst's time and effort will be deducted from (i.e., not included) in awards; applicants should not include this as a line-item in their budget but should clearly describe the analyst's role in their application and budget justification.

Application Process. This is a two-step application process, with applicants first submitting a letter of intent (LOI; one page) and then a full application (three pages), if invited to do so. Investigators invited to submit a full proposal will meet with a PPG-assigned mentor prior to submitting their full application. If interested in working with a specific PPG investigator, applicants should note this preference in the LOI.

Review Process. A review panel will recommend pilot projects for funding, contingent on NIA approval. Review will focus on alignment with the PPG and solicitation, scientific merit (overall impact, pragmatism, integration with PPG, significance, and approach), and likelihood of leading towards funding for embedded pragmatic research.

Requirements. Awardees are required to: (1) provide updates on their pilot project and related publications and grants, as requested; (2) submit a final narrative report and financial report at the end of the pilot period; and (3) present pilot project results at a PPG meeting (virtually or in-person). If presenting in person, awardees need not budget for travel, but reimbursement will be capped at $1,000.

Instructions. LOIs and full applications, if invited, must include the components below. Applicants should ensure they clearly articulate how their proposed projects relate both to ADRD and to preparing to develop or test an intervention for future testing using embedded pragmatic methods.

Letter of intent. LOIs are due by **5pm ET on Monday, November 14, 2022** and must include:

1) Letter of intent, including project title, dates, and total cost, along with the PI's name, affiliation, address, telephone, and email (this does not need to be signed by an authorized signatory at the LOI stage)
2) Specific aims
3) Research strategy
4) Literature cited
5) Budget and related budget justification
6) Biosketch for the PI and key personnel, adhering to the new NIH biosketch format requirements

LOIs are limited to one page (Arial 11pt font, ½ inch margins). The one page includes the specific aims and research strategy; title page, literature cited, budget, and biosketches do not count towards the page limit. *Applications that do not meet NIH formatting guidelines (SF424) will not be considered and appendices are not permitted.*

Full application. Invited applications are due by **5pm ET on Monday, January 30, 2023** and must include #1-6 above, with #1 signed by an authorized official, and:

7) PHS 398 face and budget pages
8) Any letters of support or commitment, if applicable
9) Human Subject Study Record: PHS Human Subjects and Clinical Trials Information Form, adhering to NIH requirements, if applicable

Full applications are limited to three pages (Arial 11pt font, ½ inch margins). The three pages include the specific aims and research strategy. The title page, literature cited, PHS 398 face and budget pages, letters of support or commitment, PHS Human Subjects and Clinical Trials Information Forms, and biosketches do not count towards the page limit. Applicants will have the opportunity to meet with their assigned PPG mentor prior to submitting their full application. *As with the LOI, applications that do not meet NIH formatting guidelines (SF424) will not be considered and appendices are not permitted.*

Submission. Applicants should email LOI and application materials to Jenna_Wahl@brown.edu. LOIs and applications should be submitted as single PDFs (combined in one file, in the order listed above) with the exception of the Study Record: PHS Human Subjects and Clinical Trials Information Form which should be submitted as a separate PDF file to the full application.

Timeline

Letters of intent due:	5pm ET on November 14, 2022
Full applications invited:	By December 5, 2022
Consultation with PPG mentor:	By January 12, 2022
Full applications due:	5pm ET on January 30, 2023
Anticipated award announcement:	Approximately May 1, 2023*
Anticipated award start date:	June 1, 2023*

**Dependent on NIA review and approval*

Questions. Applicants should direct questions to Jenna_Wahl@brown.edu. Any questions submitted by October 21, 2022 will be posted in a FAQ document on the LTCFocus ADRD Pilot Projects webpage.

Resources. Attachment A details the PPG's national data holdings (Attachment A). The PPG also maintains the LTCFocus website. Applicants can visit LTCFocus to see examples of past pilot projects and work by PPG investigators. Investigators affiliated with Brown also have Researchers@Brown profiles. Please visit NIH's website for information regarding their guidelines for submission (SF424). Additionally, for information regarding the Human Subject Study Record: PHS Human Subjects and Clinical Trials Information Form, please review the PHS Human Subjects and Clinical Trials Information section starting on page 246 of SF424.

Attachment A: Brown University CMS Data Holdings, Data Use Agreement #18900

	Year(s)																					
	'99-00	'01	'02	'03	'04	'05	'06	'07	'08	'09	'10	'11	'12	'13	'14	'15	'16	'17	'18	'19	'20	'21	'22
Assessment data																							
100% MDS (v2 and v3)[a]	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	Q1-Q3	
100% OASIS data						✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		
100% IRF-PAI data								✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		
Enrollment data (denominator/MBSF)																							
100% base file	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		
100% CCW chronic conditions (27) segment							✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		
100% CCW chronic conditions (30) segment																		✓	✓	✓	✓		
100% CCW other chron. cond. segment		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		
100% CCW cost and use segment							✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		
Part A Claims																							
Home Health																							
100% FFS Medicare population								✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		
NH cohort with FFS Medicare	✓	✓	✓	✓	✓	✓	✓																
Hospice[b]																							
100% Medicare population							✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		
NH cohort with Medicare	✓	✓	✓	✓	✓	✓	✓																
Inpatient																							
100% FFS Medicare population								✓	✓	✓	✓												
NH cohort with FFS Medicare	✓	✓	✓	✓	✓	✓	✓																
100% MEDPAR (IP/SNF claims)[c]									✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		

	Year(s)																					
	'99-00	'01	'02	'03	'04	'05	'06	'07	'08	'09	'10	'11	'12	'13	'14	'15	'16	'17	'18	'19	'20	'21	'22
Outpatient																							
100% FFS Medicare population								✓	✓	✓	✓							✓	✓	✓	✓		
NH cohort with FFS Medicare	✓	✓	✓	✓	✓	✓	✓																
IP/SNF/HH/Hospice/MDS/ OASIS cohort												✓	✓	✓	✓	✓	✓						
100% SNF FFS Medicare population	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		
Part B Claims (Carrier FFS)																							
20% FFS Medicare population								✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		
NH cohort with FFS Medicare	✓	✓	✓	✓	✓	✓	✓																
Part C MA Encounter Data [d]																							
Inpatient																✓			✓	✓			
SNF																✓			✓	✓			
Home Health																✓			✓	✓			
Outpatient																✓			✓	✓			
Carrier (20%)																✓			✓	✓			
Part D																							
Claims (including formulary)[b,e]																							
Long-stay NH cohort								✓	✓				✓			✓	✓	✓					
20% Medicare population file (largest % file)								✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓			
Entire NH Cohort													✓	✓	✓	✓	✓	✓	✓	✓			
Plan Characteristics														✓	✓	✓	✓	✓	✓	✓			
Prescriber Characteristics												✓	✓	✓	✓	✓	✓	✓	✓	✓			
Pharmacy Characteristics																✓	✓	✓	✓	✓			
OTHER																							
100% HEDIS data (CY)[f]						✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓		
100% REMIS	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	Q1-Q2		

	Year(s)																						
	'99-00	'01	'02	'03	'04	'05	'06	'07	'08	'09	'10	'11	'12	'13	'14	'15	'16	'17	'18	'19	'20	'21	'22
Shared Savings Program ACO Provider & Bene Level files														✓	✓	✓	✓	✓	✓				
Vital Status file	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		
EDB Pull for 9-digit zip codes																	✓	✓	✓	✓	✓	✓	✓
MD-PPAS															✓	✓	✓	✓					
Health Outcomes Study (HOS)																							
Cohorts 16-21 Analytic (includes baseline and followup surveys)[g]														✓	✓	✓	✓	✓	✓	✓	✓		
Cohort 22 Baseline																				✓			
HOS-M FIDE SNP																	✓	✓	✓	✓			
HOS-M PACE																	✓	✓	✓	✓			
MA CAHPS, PDP CAHPS																✓	✓	✓					
SUDGAP Medicare Claims & Assessments												✓	✓	✓	✓	✓							

Notes

[a] **MDS available for all nursing home residents, regardless of Medicare status**

[b] **Available for both FFS and Medicare Advantage Medicare beneficiaries**

[c] **Available for both FFS and a large proportion of Medicare Advantage Medicare beneficiaries**

[d] **Year 2015=preliminary (incomplete) and years 2018 & 2019= final (complete)**

[e] **Years 2016-2019 include Part D event data for anyone with >=1 day in the nursing home**

[f] **CY 2019 HEDIS data not reported to CMS due to the beginning of the COVID pandemic during the 2020 reporting year**

[g] **HOS baseline and follow-up surveys are collected 2 years apart. Cohort 16 Analytic file, e.g., has a baseline survey in 2013, and a follow-up survey in 2015**