PI: GAUGLER, JOSEPH E.  

Title: A Proactive Health Monitoring Intervention for Dementia Caregivers: The eNeighbor

Received: 01/23/2014  
FOA: PA13-046  
Council: 10/2014

Competition ID: FORMS-C  
FOA Title: AHRQ Health Services Research Demonstration and Dissemination Grants (R18)

1 R18 HS022836-01A1  
Dual:  
Accession Number: 3658166

IPF: 1450402  
Organization: UNIVERSITY OF MINNESOTA

Former Number:  
Department: School of Nursing

IRG/SRG: HTDS  
AIDS: N  
Expedited: N

Subtotal Direct Costs  
(excludes consortium F&A)

Year 1:  
Year 2:  
Year 3:  
Year 4:  
Year 5:  

Animals: N  
Humans: Y  
Clinical Trial: N  
Current HS Code: 20  
HESC: N

New Investigator: N  
Early Stage Investigator: N

Senior/Key Personnel:  
Organization:  
Role Category:

Joseph Gaugler Ph.D  
Regents of the University of Minnesota  
PD/PI

Appendices

Appendi
## APPLICATION FOR FEDERAL ASSISTANCE

### SF 424 (R&R)

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### 1. TYPE OF SUBMISSION*
- Pre-application
- Application
- Changed/Corrected Application

### 2. DATE SUBMITTED
- Application Identifier

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<th>2014-01-23</th>
<th>774794 Gaugler AHRQ Rev 1</th>
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### 5. APPLICANT INFORMATION

#### Applicant Name:
- Legal Name*: Regents of the University of Minnesota
- Position/Title: Grants and Contracts Administrator
- Telephone*: 612.624.5599
- Email: awards@umn.edu
- Fax Number: 612.624.4843
- Organizational DUNS*: 5559179960000

#### Applicant Address:
- Street1*: 450 McNamara Alumni Center
- Street2*: 200 Oak Street SE
- City*: Minneapolis
- County*: Hennepin
- State*: MN: Minnesota
- Province: USA: UNITED STATES
- ZIP / Postal Code*: 55455-2070

### 6. EMPLOYER IDENTIFICATION NUMBER (EIN) or (TIN)*
- 416007513

### 7. TYPE OF APPLICANT*

- H: Public/State Controlled Institution of Higher Education

### 8. TYPE OF APPLICATION*

#### New
- Resubmission
- Continuation
- Revision
- If Revision, mark appropriate box(es):
  - A. Increase Award
  - B. Decrease Award
  - C. Increase Duration
  - D. Decrease Duration
  - E. Other (specify):

#### Other (Specify):
- Small Business Organization Type
  - Women Owned
  - Socially and Economically Disadvantaged

### 9. NAME OF FEDERAL AGENCY*
- Agency for Health Care Research and Quality

### 10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER
- 93.226

### 11. DESCRIPTIVE TITLE OF APPLICANT’S PROJECT*
- A Proactive Health Monitoring Intervention for Dementia Caregivers: The eNeighbor

### 12. PROPOSED PROJECT

#### Start Date*
- 09/01/2014

#### Ending Date*
- 08/31/2019

### 13. CONGRESSIONAL DISTRICTS OF APPLICANT
- MN-005
14. PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR CONTACT INFORMATION

Prefix: Dr.  First Name*: Joseph  Middle Name: K  Last Name*: Gaugler  Suffix: Ph.D

Position/Title: Associate Professor
Organization Name*: Regents of the University of Minnesota
Department: School of Nursing
Division:
Street1*: 5-140 Weaver Densford Hall
Street2: 308 Harvard Street SE
City*: Minneapolis
County: Hennepin
State*: MN: Minnesota
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 55455-0353
Phone Number*: 612.626.2485  Fax Number: 612.626.2359  Email*: gaug0015@umn.edu

15. ESTIMATED PROJECT FUNDING

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16. IS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 12372 PROCESS?*

- a. YES  ○ THIS PREAPPLICATION/APPLICATION WAS MADE AVAILABLE TO THE STATE EXECUTIVE ORDER 12372 PROCESS FOR REVIEW ON:
  - DATE:
- b. NO  ● PROGRAM IS NOT COVERED BY E.O. 12372; OR
  ○ PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW

- I agree*

  *The list of certifications and assurances, or an Internet site where you may obtain this list, is contained in the announcement or agency specific instructions.

17. By signing this application, I certify (1) to the statements contained in the list of certifications* and (2) that the statements herein are true, complete and accurate to the best of my knowledge. I also provide the required assurances * and agree to comply with any resulting terms if I accept an award. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. (U.S. Code, Title 18, Section 1001)

- I agree*

18. SFLLL or OTHER EXPLANATORY DOCUMENTATION

File Name:

19. AUTHORIZED REPRESENTATIVE

Prefix: First Name*: Kevin  Middle Name: Last Name*: McKoskey  Suffix:

Position/Title*: Sr. Associate Director
Organization Name*: Regents of the University of Minnesota
Department: Office of Sponsored Proj Admin
Division:
Street1*: 450 McNamara
Street2: 200 Oak Street SE
City*: Minneapolis
County: Hennepin
State*: MN: Minnesota
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: 55455-2070
Phone Number*: 612.624.5599  Fax Number: 612.624.4843  Email*: awards@umn.edu

Signature of Authorized Representative*

Kevin McKoskey
Date Signed*

01/23/2014

20. PRE-APPLICATION  File Name:

21. COVER LETTER ATTACHMENT  File Name:
# 424 R&R and PHS-398 Specific Table Of Contents

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**Appendix**

*Number of Attachments in Appendix: 1*
Project/Performance Site Location(s)

Project/Performance Site Primary Location

- Organization Name: Regents of the University of Minnesota
- Duns Number: 5559179960000
- Street1*: 5-140 Weaver Densford Hall
- Street2: 308 Harvard Street SE
- City*: Minneapolis
- County: Hennepin
- State*: MN: Minnesota
- Province:
- Country*: USA: UNITED STATES
- Zip / Postal Code*: 55455-0353
- Project/Performance Site Congressional District*: MN-005

File Name

Additional Location(s)
### RESEARCH & RELATED Other Project Information

1. **Are Human Subjects Involved?**
   - [ ] Yes
   - [ ] No

   1.a. If YES to Human Subjects
   - Is the Project Exempt from Federal regulations?
     - [ ] Yes
     - [ ] No
   - If YES, check appropriate exemption number: 1 2 3 4 5 6
   - If NO, is the IRB review Pending?
     - [ ] Yes
     - [ ] No

   - IRB Approval Date:
   - Human Subject Assurance Number 00000312

2. **Are Vertebrate Animals Used?**
   - [ ] Yes
   - [ ] No

   2.a. If YES to Vertebrate Animals
   - Is the IACUC review Pending?
     - [ ] Yes
     - [ ] No

   - IACUC Approval Date:
   - Animal Welfare Assurance Number

3. **Is proprietary/privileged information included in the application?**
   - [ ] Yes
   - [ ] No

4. **Does this project have an actual or potential impact - positive or negative - on the environment?**
   - [ ] Yes
   - [ ] No

   4.a. If yes, please explain:
   4.b. If this project has an actual or potential impact on the environment, has an exemption been authorized or an environmental assessment (EA) or environmental impact statement (EIS) been performed?
   4.c. If yes, please explain:
   4.d. If yes, please explain:

5. **Is the research performance site designated, or eligible to be designated, as a historic place?**
   - [ ] Yes
   - [ ] No

6. **Does this project involve activities outside the United States or partnership with international collaborators?**
   - [ ] Yes
   - [ ] No

   6.a. If yes, identify countries:
   6.b. Optional Explanation:

7. **Project Summary/Abstract**
   - [ ] 1235-projectsummaryabstract.pdf

8. **Project Narrative**
   - [ ] 1236-projectnarrative.pdf

9. **Bibliography & References Cited**
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10. **Facilities & Other Resources**
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11. **Equipment**
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Project Summary/Abstract

Sensor-based technologies that operate remotely and are non-invasive could assist family caregivers monitor the daily function of persons with Alzheimer’s disease or a related dementia (ADRD). For example, the eNeighbor technology platform includes a combination of remote sensors that are located in key areas of a person with ADRD’s home (e.g., bed, medicine cabinet or refrigerator doors, toilet, living rooms). Such sensors can immediately communicate any function that is outside of an expected functional threshold for the person with ADRD to both a family caregiver and a care professional. The goal of remote health monitoring technology such as eNeighbor is to prevent negative health transitions such as falls or wandering events, and thus provides a more proactive intervention model than many clinical protocols that are currently delivered to family caregivers of persons with ADRD. The Lutheran Home Association, a non-profit long-term care provider located in Belle Plaine, Minnesota, has deployed eNeighbor in residential and home settings throughout Minnesota and Wisconsin over the past 5 years.

The objective of this 5-year demonstration project is to build on the work of The Lutheran Home Association and conduct an embedded experimental mixed methods evaluation to determine the efficacy of the eNeighbor technology in improving outcomes among persons with ADRD living in the community and their family caregivers. [Through ongoing engagement with a 16-member Community Advisory Board to enhance the utility of health monitoring technology for families who care for persons with ADRD, the Specific Aims are as follows]: 1) To compare 100 ADRD caregivers randomly assigned to an attention control with 100 ADRD caregivers who utilize eNeighbor over an 18-month period to determine if the use of the remote sensor technology results in a) significant ($p < .05$) increases in caregiver self-efficacy and sense of competence, b) significant decreases in caregiver distress (subjective stress, depressive symptoms), c) significant delays of or reductions in negative health transitions (falls, wandering events) and service utilization (residential care placement, hospitalizations) for persons with ADRD; and d) greater cost-effectiveness; and 2) To determine through “embedded” qualitative data collection components how eNeighbor is successfully utilized and why this health monitoring technology benefits persons with ADRD and their family caregivers. We anticipate that the successful completion of the project aims will position the eNeighbor as an innovative, stakeholder-centric approach that offers robust support for family caregivers of persons with ADRD in their communities.
Project Narrative

The Lutheran Home Association (TLHA), a non-profit long-term care provider located in Belle Plaine, Minnesota, has deployed remote health monitoring technology for older adults (“eNeighbor”) in residential and home settings across Minnesota and Wisconsin the past 5 years. The proposed demonstration project will build on TLHA’s current work by evaluating eNeighbor for 200 persons with Alzheimer’s disease or a related dementia (ADRD) and their family caregivers. We will utilize an embedded experimental mixed methods design to determine whether and how the eNeighbor technology improves ADRD caregivers’ self-efficacy and sense of competence in managing the complicated nature of ADRD symptoms, reduces ADRD caregivers’ distress, and delays or reduces negative health transitions and service use in persons with ADRD over an 18-month period. The proposed 5-year demonstration project will also engage and collaborate with a Community Advisory Board on a quarterly basis to ensure that the health monitoring technology is appropriately designed, delivered, evaluated, and disseminated for families caring for persons with ADRD. We anticipate that this innovative health monitoring intervention (which adopts a proactive approach to chronic disease care) will result in an effective protocol that offers robust support for family caregivers of persons with ADRD in their communities.
Facilities and Other Resources
How the Scientific Environment will Contribute to the Success of the Project

The University of Minnesota is a premier research institution and the School of Nursing is among the top 20-ranked nursing programs in obtaining National Institutes of Health (NIH) funding (2010). As summarized below, the Principal Investigator/PI (Dr. Gaugler) has access to strong infrastructural support in the University of Minnesota’s School of Nursing including ample research office space, shared servers, and multiple research-specific computers to complete the proposed activities.

The Clinical and Translational Science Institute (CTSI; the University of Minnesota CTSI was awarded a Clinical Translational Science Award in 2011; 1UL1RR033183) provides a single point of access to resources and expertise that supports successful clinical and translational research, including investigator-initiated and industry-sponsored studies. The CTSI integrates the Academic Health Center and other University resources with community partners to create a comprehensive statewide network for clinical and translational science. CTSI’s comprehensive research services include: expertly trained support staff, biostatistical design and analysis, regulatory support, and clinical research facilities (see http://www.ctsi.umn.edu). As outlined below, the proposed project will rely on three key CTSI components to successfully complete the study aims: the Biostatistical Design and Analysis Center, the Biomedical Informatics Core, and the Delaware Clinical Research Unit.

The Lutheran Home Association (TLHA), a private, nonprofit 501(c) (3) corporation established in 1973, provides a broad range of health care, housing, rehabilitation and service options for older adults and persons with disabilities at several locations throughout Minnesota and Wisconsin. The Lutheran Home Association owns and operates skilled nursing homes, 154 independent living units, 103 assisted living units, 14 memory care units, 24 Section 202 housing units for the elderly and 8 section 811 housing units for persons with disabilities. TLHA has developed cutting edge systems, service coordination and support models which successfully assist older adults and persons with disabilities to continue to live independently in their community homes. Over the past five years, TLHA has successfully implemented and utilized remote health monitoring systems within independent, assisted living and memory care units as well as low income housing apartments and private homes. The impact realized by older adults significantly prolonged the need to move into a more costly care setting. Outcome reporting data and case examples also supported that the implementation of this technology enabled care model resulted in increased independence and improved health status. In addition, this cost effective service model has also demonstrated that it served to provide predictive health care data analytics and preemptive care interventions.

Clinical

The metropolitan areas of Minneapolis/St. Paul and greater Minnesota have a rich resource of health care agencies and service organizations. There is a strong tradition of support and cooperation between these urban and rural agencies and the University of Minnesota. The School of Nursing contracts with over 300 sites. Affiliation agreements with these organizations facilitate faculty research and clinical education.

Computer

Computer facilities at the University of Minnesota range from micro-computing laboratories to state-of-the-art supercomputers interconnected by a fiber-optic Ethernet backbone. Through the customizable MyU portal, faculty, staff and students have access to online courses, library resources, and an extensive system of computer services for research and instruction. Numerous additional computers are available to staff at their workstations and to students in the doctoral student offices and computer laboratories. A variety of software packages is available, including LISREL, M-Plus, NVivo, SAS-PC, SPSS, Excel, Word, WordPerfect, Harvard Graphics, Access, Skype, Adobe Presenter, Adobe Acrobat Professional, and FileMaker Pro. University Office of Information Technology consultants are available to help faculty, staff, and students identify and plan how to effectively apply digital technologies without charge (http://www.oit.umn.edu/consultation-services/index.htm).

Within the Academic Health Center (AHC), the AHC Information Systems office provides desktop support, server operations, hardware and software purchasing assistance, and application development services. Its Research Development and Support team develops and supports research related applications including scheduling, research participant tracking, and protocol and study tracking. The team works with various research studies and AHC areas including the CTSI (http://www.ahc.umn.edu/facultystaff/ahcis/index.htm).
Office

The office of Dr. Gaugler in the School of Nursing is approximately 125 square feet and is equipped with a personal computer (including the necessary statistical software), laser printer, web camera, telephone access, and ample file space to conduct the proposed study. The computer has LAN access.

The mission of the University of Minnesota School of Nursing is to generate knowledge and to prepare nurse leaders who will create, guide, and participate in holistic and multisectoral efforts to improve the health of all people within the context of their environment. Established in 1909, the University of Minnesota’s School of Nursing is the oldest nursing school on a university campus in the United States. The school has two locations: one in the heart of the vital and progressive Twin Cities of Minneapolis and St. Paul, and the second in Rochester, home of the Mayo Clinic. Original scholarly inquiry is the core of the rich synergy of research, education, and practice at the University of Minnesota School of Nursing. Opportunities for collaborative research abound with nursing colleagues, colleagues from other disciplines at Minnesota’s renowned Academic Health Center and other academic areas throughout the University, and community partners in this progressive, health-oriented community. Focal areas of research in the School of Nursing include: 1) health promotion among vulnerable populations; 2) prevention and management of chronic health conditions; 3) symptom management; and 4) health/nursing informatics and systems improvement (http://www.nursing.umn.edu/research). The School of Nursing offers a BSN program, a Master of Nursing program, a Doctorate of Nursing Practice program, and Minnesota’s only PhD program. The programs draw upon the rich research resources and community connections of the University of Minnesota to provide a learning environment for nurses who come to the school from around the state, nation, and world. The research-rich environment is ideal to prepare practicing nurses, nurse leaders, nurse researchers, and nurse educators.

The School of Nursing is housed in Weaver-Densford Hall (WDH), which includes approximately 35,000 square feet of teaching, research, and office facilities. As of August, 2008 additional research space for project staff has been available in the Dinnaken Office Building which is located approximately 4 city blocks from faculty and administrative offices (Dr. Gaugler’s research staff are located in Dinnaken Office Building). Available resources include offices, conference rooms, telephone, fax, and secure confidential data storage areas.

Other

As part of his academic appointment in The School of Nursing, Dr. Gaugler will have the necessary time to devote to the proposed project. The teaching load is flexible and based on external support for Dr. Gaugler’s research time. Service expectations include standard membership on departmental and university committees. Due to the advantageous research environment provided by The School of Nursing, Dr. Gaugler can devote up to 95% of his time to research projects, and he will have the necessary effort available to make the current project a success.

The University of Minnesota has been rated among the nation’s top 10 public research universities. More than 60,000 students are enrolled in 17 different colleges and schools on the Twin Cities Campus. The Graduate School offers more than 150 Master’s and doctoral degree programs covering virtually every area of academic inquiry. The wide breadth of program offerings provides graduate students with multiple opportunities for interdisciplinary study.

The Academic Health Center (AHC), one of the most comprehensive health education and research centers in the United States, is composed of the Schools of Nursing, Medicine, Dentistry, Pharmacy, Public Health, and Veterinary Medicine. Strong interdisciplinary centers and programs in bioethics, cancer, genomics, infectious disease, drug design, food safety, and spirituality and healing provide a broad range of professional health education and research opportunities. The AHC is located in the heart of the University of Minnesota on the Twin Cities campus (http://www.ahc.umn.edu/). A number of AHC and University-wide interdisciplinary research and education centers exist and include School of Nursing faculty as active members or participants. Those of direct relevance to this proposed project include the following:

The mission of the School of Nursing’s Center for Gerontological Nursing (CGN) (Director: Jean Wyman, PhD, RN, GNP-BC, FAAN, FGSA) is to lead gerontological nursing research, education, and practice by generating new knowledge, disseminating findings, and translating research into practice that is important locally and globally to improve the health of older individuals, their families, communities, and populations. Twenty-four CGN faculty conduct research on health promotion, symptom management, health restoration, and care delivery for elders. The Center facilitates career development; fosters collaborative efforts among faculty, students, and the community related to gerontological nursing research; and promotes research dissemination. Center activities include a mentorship program, research seminars, peer review of grant
proposals and manuscripts, and collaborations with community organizations and agencies. The Center received funding from the John A. Hartford Foundation’s Nursing School Geriatric Investment Program and the Creating Careers in Geriatric Nursing Program. The CGN participates as a regional site for the University of Iowa’s Gerontological Nursing Intervention Research Center (http://www.nursing.umn.edu/cgn/index.htm). The CGN also housed an exploratory P20 NIH-NINR research center, “Center for Health Trajectory Research” (1 P20 NR008992); research supported by the P20 was featured in a special issue of Nursing Research (2011, volume 60, supplement 3) in which the Principal Investigator of the proposed project and CGN member, Dr. Gaugler, authored two articles.

The Center on Aging (CoA) has been the focal point of aging research at the University of Minnesota for nearly 26 years. The mission of the CoA is to facilitate the University’s response to societal issues of an aging population by fostering basic and applied research as well as education that will help explicate the aging process and inform public policy. It provides opportunities for interdisciplinary collaboration and learning for those dedicated to understanding the challenges faced by older persons and to optimizing their health and well-being. Faculty and students from 22 departments or schools in the University are CoA members. The CoA engages in a variety of activities such as administering the graduate interdisciplinary minor in gerontology, publishing a quarterly newsletter, offering an interdisciplinary research seminar series, hosting an annual lecture and visit presented by a scholar with national recognition in aging, providing annual student research grants, and evaluating candidates for the Fesler-Lambert Chair in Aging (http://www.coa.umn.edu). The objective of the Mixed Methods Interdisciplinary Graduate Group (MMIGG; Dr. Gaugler is the founder and director) is to expand understanding of the integration and synthesis of qualitative and quantitative methods of scientific inquiry (http://www.grad.umn.edu/projects-priorities/idinitiatives/groups/mixedmethods/index.html). The focus of this group is to examine the philosophy/paradigmatic underpinnings of mixed methods research, types of mixed methods designs, key methodological issues of concern (sampling, measurement, and analysis), synthesis and dissemination of mixed methods research, and quality in mixed methods research. A main objective is to create a critical mass of researchers to develop interdisciplinary, collaborative research initiatives. The MMIGG provides interested researchers with peer review services, consultation, and collaborative partnerships to advance mixed methods research and pedagogy. There are over 100 individuals involved in the MMIGG throughout the University of Minnesota. A virtual library houses meeting summaries and other resources pertaining to the MMIGG (http://tinyurl/MMIGGlibrary).

The following Clinical and Translational Science Institute components will be utilized for the proposed project:

The Biostatistical Design and Analysis Center (BDAC) provides statistical and data management support from study design to final analysis and publication of results. BDAC offers comprehensive assistance on study design consultation and evaluation (sample size and power calculations; grant proposals development), data management (database dictionary and documentation; design of web-based interface for data entry; quality control programs to monitor data integrity; data quality reports), statistical analysis (clinical trial monitoring and interim analyses; multi-level data analysis; tables, graphs and summarization of analysis results; interpretation of results) and manuscript preparation and review. BDAC uses an extensive computer network of SUN workstations (UNIX operating system), graphics terminals, microcomputers, scanners, and laser printers. This results in a large scale, high-speed computer system capable of handling many projects simultaneously. The system is backed up daily so files can be easily archived and retrieved. The network supports a variety of software, including SAS, S-Plus and R. Connection to the University Ethernet facilitates interaction with other computers and to the Internet. All BDAC personnel have access to personal computers (PCs), which have been installed with commonly used software for word processing and data management. Files are easily transferred between these computers and the network. All BDAC PCs are password protected. Philippe Gaillard, PhD, Research Associate in BDAC, will provide biostatistical support on the proposed project (see Personnel Justification).

The Biomedical Informatics (BMI) core translates data into useful information to improve the health of individuals and populations. Connie White Delaney, PhD, RN, FAAN, FACMI, Dean of the School of Nursing, is Director of the BMI core. Key activities to date include the establishment of the Office of Biomedical Health Informatics (BMHI). BMHI collaborates and provides leadership for the Coordinated University Interdisciplinary Informatics initiatives; leverages the academic expertise of the Institute for Health Informatics (IHI; the University of Minnesota academic home for BMI research and education); collaborates on the development and leadership for the Center for eHealth (a collaboration with the State of Minnesota); and operationalized the BMI effort through the Academic Health Center Information Exchange structure to meet CTSI BMI goals at the University. The BMHI utilizes an extensive cadre of BMI experts to support clinicians and scientists; construct
and maintain infrastructure; educate the next generation of biomedical informaticians; build bridges to clinical information; connect researchers with controlled access to clinical data and biological samples with broad coverage of populations and healthcare delivery participants; and provide easy access to BMI resources and tools through a “Front Door” single point-of-contact. These interactions serve as the basis for ongoing tool enhancement and to apply research to improve health in communities. The proposed project will rely on two BMI services: the REDCap (Research Electronic Data Capture) web-based system for data collection and management, and UMN Profiles, a research networking software tool and expertise database to connect the findings of this project to the broader research community (see Letters of Support and Resource Sharing Plan section).

The Delaware Clinical Research Unit (DCRU) is a 36,750 square foot outpatient facility including separate adult and pediatric oriented facilities. Adult facilities include 10 exam rooms, 4 consultation rooms, 5 specialized rooms, a metabolic kitchen, a sample acquisition room, and an on-site laboratory. The facility provides 23 free parking spaces for research participants. Pediatric facilities include 12 pediatric exam rooms, 6 electrically silent rooms permitting evoked response potential measurement, 6 rooms with hidden cameras to allow observation from a different room, and a well-equipped waiting room. The DCRU is within 2 blocks of Dr. Gaugler’s office in Weaver-Densford Hall and his research staff offices in the Dinnaken Office Building. The DCRU will be utilized if participants wish to complete their interviews at the University of Minnesota (see Research Strategy section).
Equipment

[Fifty] eNeighbor multi-sensor packages will be installed and used in the current project. The cost of each multi-sensor unit is and includes 1 emergency call pendant, 4 motion sensors (front entry, living room, bedroom, and bathroom), 3 contact points (front door, cabinet, and refrigerator), a toilet sensor, a bed sensor, and a cancel button. A installation fee is also included. In order to control costs on the proposed project, [Year 1 and Year 2 up-front costs are budgeted.] After the first [50] persons with Alzheimer’s disease or a related disorder (ADRD) and their family caregivers complete their 18 months of participation in the eNeighbor treatment condition (Years 3-4), the sensor equipment will be re-used and installed in [50] additional homes of persons with ADRD (Years 3-5) thus allowing for the availability of eNeighbor for the entire treatment sample \( n = 100 \). This will avoid the high up-front costs associated with purchasing 100 units and yet still allow for use of the eNeighbor for 100 persons with ADRD and their family caregivers over an 18-month period. [In addition, the 50 purchased remote sensor packages will be offered for free over a 1.5-year period on a first-come, first-serve basis to families in the usual care control condition who wish to use eNeighbor at the conclusion of the randomized controlled phase].
### RESEARCH & RELATED Senior/Key Person Profile (Expanded)

#### PROFILE - Project Director/Principal Investigator

<table>
<thead>
<tr>
<th>Prefix: Dr.</th>
<th>First Name*: Joseph</th>
<th>Middle Name</th>
<th>Last Name*: Gaugler</th>
<th>Suffix: Ph.D</th>
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<tr>
<td><strong>Phone Number</strong>:</td>
<td>612.626.2485</td>
<td><strong>Fax Number</strong>:</td>
<td>612.626.2359</td>
<td><strong>E-Mail</strong>: <a href="mailto:gaug0015@umn.edu">gaug0015@umn.edu</a></td>
</tr>
<tr>
<td><strong>Credential, e.g., agency login</strong>:</td>
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#### PROFILE - Senior/Key Person

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<thead>
<tr>
<th>Prefix: Dr.</th>
<th>First Name*: Bonnie</th>
<th>Middle Name</th>
<th>Last Name*: Westra</th>
<th>Suffix: Ph.D</th>
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<td><strong>Phone Number</strong>:</td>
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<td><strong>Fax Number</strong>:</td>
<td>612.626.3225</td>
<td><strong>E-Mail</strong>: <a href="mailto:westr006@umn.edu">westr006@umn.edu</a></td>
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Contact PD/PI: Gaugler, Joseph, K
BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2. Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

<table>
<thead>
<tr>
<th>NAME</th>
<th>POSITION TITLE</th>
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</thead>
<tbody>
<tr>
<td>Gaugler, Joseph E.</td>
<td>Associate Professor; McKnight Presidential Fellow, School of Nursing, University of Minnesota</td>
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B. Positions and Honors

Other Experience and Professional Memberships

Honors

(b) (6)
C. Selected Peer-Reviewed Publications (selected from 78 peer-reviewed publications)

Additional recent publications of importance to the field (in chronological order)

Contact PD/PI: Gaugler, Joseph, K(b) (6)
BIOGRAPHICAL SKETCH

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**EDUCATION/TRAINING** *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

| (b) (6)                  |                        |         |                |

**B. Positions and Honors**

| (b) (6)                  |                        |         |                |

Contact PD/PI: Gaugler, Joseph, K
Other Experience and Professional Memberships

C. Selected Peer-Reviewed Publications
D. Research Support

Contact PD/PI: Gaugler, Joseph, K
### BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors in the order listed on Form Page 2. Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

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#### EDUCATION/TRAINING

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#### A. Personal Statement

(b) (6)

#### B. Positions and Honors

(b) (6)

Professional and panel memberships

(b) (6)
C. Selected Peer-reviewed Publications (relevant to proposal)

Additional recent publications of importance to the field

D. Research Support
   Ongoing Research Support
Volunteer and Other Professional Experience

Professional Memberships

Honors

C. Selected Peer-Reviewed Publications
C. Ongoing Research Support

Completed Research Support
**BIOGRAPHICAL SKETCH**

Provide the following information for the Senior/key personnel and other significant contributors in the order listed on Form Page 2. Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

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**A. Personal Statement**

(b) (6)

**B. Positions and Honors**

(b) (6)
C. Selected Peer-reviewed Publications
D. Research Support

(6)

(b) (6)
BIOGRAPHICAL SKETCH

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A. Personal Statement

(b) (6)

B. Positions and Honors.

(b) (6)
C. Selected peer-reviewed publications (in chronological order, out of 138 total)

D. Research Support
### BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2. Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

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#### A. Personal Statement

(b) (6)

#### B. Positions and Honors

(b) (6)

#### Other Experience and Professional Memberships

(b) (6)
C. Selected peer-reviewed publications (selected from 32 peer-reviewed publications)
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**EDUCATION/TRAINING** *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

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**A. Personal Statement**

| (b) | (6) |

**B. Positions and Honors.**

**Positions and Employment**

| (b) | (6) |

**Professional Membership**

| (b) | (6) |

**C. Peer-reviewed publications (in chronological order)**

| (b) | (6) |
D. Research Support
### A. Senior/Key Person

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<tr>
<th>Prefix</th>
<th>First Name*</th>
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<th>Project Role*</th>
<th>Base Salary ($)</th>
<th>Calendar Months</th>
<th>Academic Months</th>
<th>Summer Months</th>
<th>Requested Salary ($)*</th>
<th>Fringe Benefits ($)*</th>
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<td>K</td>
<td>Gaugler</td>
<td>Ph.D</td>
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**Total Funds Requested for all Senior Key Persons in the attached file**

**Additional Senior Key Persons:**

**Total Senior/Key Person:** (b) (6)

### B. Other Personnel

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**Total Number Other Personnel**

**Total Other Personnel**

**Total Salary, Wages and Fringe Benefits (A+B):** (b) (6)
### C. Equipment Description

List items and dollar amount for each item exceeding $5,000

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Total funds requested for all equipment listed in the attached file

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Additional Equipment: File Name:

### D. Travel

1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)
2. Foreign Travel Costs

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<th>Total Travel Cost</th>
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### E. Participant/Trainee Support Costs

1. Tuition/Fees/Health Insurance
2. Stipends
3. Travel
4. Subsistence
5. Other:

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<th>Number of Participants/Trainees</th>
<th>Total Participant Trainee Support Costs</th>
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RESEARCH & RELATED Budget (C-E) (Funds Requested)
**ORGANIZATIONAL DUNS**: 5559179960000  
**Budget Type**: ● Project  ○ Subaward/Consortium  
**Organization**: Regents of the University of Minnesota  

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**F. Other Direct Costs**
- 1. Materials and Supplies
- 2. Publication Costs
- 3. Consultant Services
- 4. ADP/Computer Services
- 5. Subawards/Consortium/Contractual Costs
- 6. Equipment or Facility Rental/User Fees
- 7. Alterations and Renovations
- 8. Duplication Cost
- 9. Transcription Service

**Total Other Direct Costs**

**G. Direct Costs**

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**H. Indirect Costs**

**Total Indirect Costs**

**I. Total Direct and Indirect Costs**

**Total Direct and Indirect Institutional Costs (G + H)**

**J. Fee**

**K. Budget Justification**

File Name: 1234-UofMbudgetjustification.pdf  
(Only attach one file.)
# RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 2

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**Budget Type**: ● Project ○ Subaward/Consortium  
**Enter name of Organization**: Regents of the University of Minnesota  

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## A. Senior/Key Person

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Total Funds Requested for all Senior Key Persons in the attached file

**Additional Senior Key Persons**: File Name: Total Senior/Key Person (b) (6)

## B. Other Personnel

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Total Number Other Personnel  

**Total Other Personnel**  

**Total Salary, Wages and Fringe Benefits (A+B)** (b) (6)
### Research & Related Budget - Section C, D, & E, Budget Period 2

**Organizational DUNS**: 5559179960000

**Budget Type**:  ● Project  ○ Subaward/Consortium

**Organization**: Regents of the University of Minnesota

**Start Date**: 09-01-2015  **End Date**: 08-31-2016  **Budget Period**: 2

#### C. Equipment Description

List items and dollar amount for each item exceeding $5,000

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**Total Equipment**

**Additional Equipment**: File Name:

#### D. Travel

1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)
2. Foreign Travel Costs

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<tr>
<th>Number of Participants/Trainees</th>
<th>Total Participant Trainee Support Costs</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

RESEARCH & RELATED Budget (C-E) (Funds Requested)
### ORGANIZATIONAL DUNS*:
5559179960000

### Budget Type*:
- ⬤ Project
- ☐ Subaward/Consortium

### Organization:
Regents of the University of Minnesota

#### Start Date*:
09-01-2015

#### End Date*:
08-31-2016

#### Budget Period:
2

### F. Other Direct Costs

<table>
<thead>
<tr>
<th>Item</th>
<th>Funds Requested ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Materials and Supplies</td>
<td></td>
</tr>
<tr>
<td>2. Publication Costs</td>
<td></td>
</tr>
<tr>
<td>3. Consultant Services</td>
<td></td>
</tr>
<tr>
<td>4. ADP/Computer Services</td>
<td></td>
</tr>
<tr>
<td>5. Subawards/Consortium/Contractual Costs</td>
<td></td>
</tr>
<tr>
<td>6. Equipment or Facility Rental/User Fees</td>
<td></td>
</tr>
<tr>
<td>7. Alterations and Renovations</td>
<td></td>
</tr>
<tr>
<td>8. Duplication Costs</td>
<td></td>
</tr>
<tr>
<td>9. Transcription Services</td>
<td></td>
</tr>
</tbody>
</table>

#### Total Other Direct Costs

### G. Direct Costs

#### Total Direct Costs (A thru F)

### H. Indirect Costs

<table>
<thead>
<tr>
<th>Indirect Cost Type</th>
<th>Indirect Cost Rate (%)</th>
<th>Indirect Cost Base ($)</th>
<th>Funds Requested ($)</th>
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</thead>
<tbody>
<tr>
<td>1. MDTC</td>
<td>52.00</td>
<td>161,539.00</td>
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</table>

#### Total Indirect Costs

#### Cognizant Federal Agency

- DHHS, Arif Karim, 214-767-3600

### I. Total Direct and Indirect Costs

#### Total Direct and Indirect Institutional Costs (G + H)

### J. Fee

#### Funds Requested ($)*

### K. Budget Justification*

- File Name: 1234-UofMbudgetjustification.pdf
- (Only attach one file.)
**RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 3**

**ORGANIZATIONAL DUNS**: 5559179960000

**Budget Type**: ● Project ○ Subaward/Consortium

**Enter name of Organization**: Regents of the University of Minnesota

**Start Date**: 09-01-2016  **End Date**: 08-31-2017  **Budget Period**: 3

---

### A. Senior/Key Person

<table>
<thead>
<tr>
<th>Prefix</th>
<th>First Name*</th>
<th>Middle Name</th>
<th>Last Name*</th>
<th>Suffix</th>
<th>Project Role*</th>
<th>Base Salary ($)</th>
<th>Calendar Months</th>
<th>Academic Months</th>
<th>Summer Months</th>
<th>Requested Salary ($)*</th>
<th>Fringe Benefits ($)*</th>
<th>Funds Requested ($)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr.</td>
<td>Joseph</td>
<td>K</td>
<td>Gaugler</td>
<td>Ph.D</td>
<td>PD/PI</td>
<td>(b) (6)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons:  

File Name:

Total Senior/Key Person (b) (6)

---

### B. Other Personnel

<table>
<thead>
<tr>
<th>Number of Personnel*</th>
<th>Project Role*</th>
<th>Calendar Months</th>
<th>Academic Months</th>
<th>Summer Months</th>
<th>Requested Salary ($)*</th>
<th>Fringe Benefits*</th>
<th>Funds Requested ($)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post Doctoral Associates</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Graduate Students</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Undergraduate Students</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Secretarial/Clerical</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Research Coordinator</td>
<td></td>
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<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1  

Total Number Other Personnel (b) (4)

Total Salary, Wages and Fringe Benefits (A+B)

---

RESEARCH & RELATED Budget (A-B) (Funds Requested)
### C. Equipment Description

List items and dollar amount for each item exceeding $50,000.

<table>
<thead>
<tr>
<th>Equipment Item</th>
<th>Funds Requested ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Total funds requested for all equipment listed in the attached file: 

**Total Equipment**

Additional Equipment: File Name:

### D. Travel

1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)
2. Foreign Travel Costs

**Total Travel Cost**

### E. Participant/Trainee Support Costs

1. Tuition/Fees/Health Insurance
2. Stipends
3. Travel
4. Subsistence
5. Other:

<table>
<thead>
<tr>
<th>Number of Participants/Trainees</th>
<th>Total Participant Trainee Support Costs</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

RESEARCH & RELATED Budget {C-E} (Funds Requested)
## RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 3

### ORGANIZATIONAL DUNS*
5559179960000

### Budget Type*
- [ ] Project
- [x] Subaward/Consortium

### Organization
Regents of the University of Minnesota

### Start Date*
09-01-2016  
### End Date*
08-31-2017  
### Budget Period
3

#### F. Other Direct Costs

<table>
<thead>
<tr>
<th>Description</th>
<th>Funds Requested ($)</th>
<th>(b) (4)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Materials and Supplies</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Publication Costs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Consultant Services</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. ADP/Computer Services</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Subawards/Consortium/Contractual Costs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Equipment or Facility Rental/User Fees</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Alterations and Renovations</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. Duplication costs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9. Transcription Services</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| Total Other Direct Costs                 |                     |         |

#### G. Direct Costs

| Total Direct Costs (A thru F)            | (b) (4) |

#### H. Indirect Costs

<table>
<thead>
<tr>
<th>Indirect Cost Type</th>
<th>Indirect Cost Rate (%)</th>
<th>Indirect Cost Base ($)</th>
<th>Funds Requested ($)</th>
<th>(b) (4)</th>
</tr>
</thead>
<tbody>
<tr>
<td>MDTC</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| Total Indirect Costs | (b) (4) |

### Cognizant Federal Agency
DHHS, Arif Karim, 214-767-3600

#### I. Total Direct and Indirect Costs

| Total Direct and Indirect Institutional Costs (G + H) | (b) (4) |

#### J. Fee

| Funds Requested ($) | (b) (4) |

#### K. Budget Justification*

- File Name: 1234-UofMbudgetjustification.pdf
- (Only attach one file.)

---

RESEARCH & RELATED Budget (F-K) (Funds Requested)
### RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 4

**ORGANIZATIONAL DUNS**: 5559179960000  
**Budget Type**: ● Project ○ Subaward/Consortium  
**Enter name of Organization**: Regents of the University of Minnesota  
**Start Date**: 09-01-2017  
**End Date**: 08-31-2018  
**Budget Period**: 4

#### A. Senior/Key Person

<table>
<thead>
<tr>
<th>Prefix</th>
<th>First Name*</th>
<th>Middle Name</th>
<th>Last Name*</th>
<th>Suffix</th>
<th>Project Role*</th>
<th>Base Salary ($)</th>
<th>Calendar Months</th>
<th>Academic Months</th>
<th>Summer Months</th>
<th>Requested Salary ($)*</th>
<th>Fringe Benefits ($)*</th>
<th>Funds Requested ($)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr.</td>
<td>Joseph</td>
<td>K</td>
<td>Gaugler</td>
<td></td>
<td>PD/PI</td>
<td>(b) (6)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Total Senior/Key Person**: (b) (6)

**Additional Senior Key Persons**:  
**File Name**:  
**Total Senior/Key Person**: (b) (6)

#### B. Other Personnel

<table>
<thead>
<tr>
<th>Number of Personnel*</th>
<th>Project Role*</th>
<th>Calendar Months</th>
<th>Academic Months</th>
<th>Summer Months</th>
<th>Requested Salary ($)*</th>
<th>Fringe Benefits*</th>
<th>Funds Requested ($)*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Post Doctoral Associates</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Graduate Students</td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Undergraduate Students</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Secretarial/Clerical</td>
<td>Research Coordinator</td>
<td>[b] [4]</td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**1 Total Number Other Personnel**: (b) (4)

**Total Salary, Wages and Fringe Benefits (A+B)**: (b) (4)
**RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 4**

**ORGANIZATIONAL DUNS**: 5559179960000

**Budget Type**:  ● Project  ○ Subaward/Consortium

**Organization**: Regents of the University of Minnesota

**Start Date**: 09-01-2017  **End Date**: 08-31-2018  **Budget Period**: 4

### C. Equipment Description

List items and dollar amount for each item exceeding $5,000

<table>
<thead>
<tr>
<th>Equipment Item</th>
<th>Funds Requested ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total funds requested for all equipment listed in the attached file</td>
<td>Total Equipment</td>
</tr>
</tbody>
</table>

**Additional Equipment**: File Name:

### D. Travel

1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)
2. Foreign Travel Costs

**Total Travel Cost**

### E. Participant/Trainee Support Costs

1. Tuition/Fees/Health Insurance
2. Stipends
3. Travel
4. Subsistence
5. Other:

<table>
<thead>
<tr>
<th>Number of Participants/Trainees</th>
<th>Total Participant Trainee Support Costs</th>
</tr>
</thead>
</table>

RESEARCH & RELATED Budget {C-E} (Funds Requested)
## RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 4

### ORGANIZATIONAL DUNS*:
- 5559179960000

### Budget Type*:
- ● Project
- ○ Subaward/Consortium

### Organization:
- Regents of the University of Minnesota

### Start Date*: 09-01-2017  
### End Date*: 08-31-2018  
### Budget Period: 4

#### F. Other Direct Costs

<table>
<thead>
<tr>
<th>Item</th>
<th>Funds Requested ($)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Materials and Supplies</td>
<td>(b) (4)</td>
</tr>
<tr>
<td>2. Publication Costs</td>
<td>(b) (4)</td>
</tr>
<tr>
<td>3. Consultant Services</td>
<td>(b) (4)</td>
</tr>
<tr>
<td>4. ADP/Computer Services</td>
<td>(b) (4)</td>
</tr>
<tr>
<td>5. Subawards/Consortium/Contractual Costs</td>
<td>(b) (4)</td>
</tr>
<tr>
<td>6. Equipment or Facility Rental/User Fees</td>
<td>(b) (4)</td>
</tr>
<tr>
<td>7. Alterations and Renovations</td>
<td>(b) (4)</td>
</tr>
<tr>
<td>8. Duplication costs</td>
<td>(b) (4)</td>
</tr>
<tr>
<td>9. Transcription Services</td>
<td>(b) (4)</td>
</tr>
</tbody>
</table>

**Total Other Direct Costs**

#### G. Direct Costs

<table>
<thead>
<tr>
<th>Funds Requested ($)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Direct Costs (A thru F)</td>
</tr>
</tbody>
</table>

#### H. Indirect Costs

<table>
<thead>
<tr>
<th>Indirect Cost Type</th>
<th>Indirect Cost Rate (%)</th>
<th>Indirect Cost Base ($)</th>
<th>Funds Requested ($)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. MDTC</td>
<td>(b) (4)</td>
<td>(b) (4)</td>
<td>(b) (4)</td>
</tr>
</tbody>
</table>

**Total Indirect Costs**

**Cognizant Federal Agency**
- DHHS, Arif Karim, 214-767-3600

#### I. Total Direct and Indirect Costs

<table>
<thead>
<tr>
<th>Funds Requested ($)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Direct and Indirect Institutional Costs (G + H)</td>
</tr>
</tbody>
</table>

#### J. Fee

<table>
<thead>
<tr>
<th>Funds Requested ($)*</th>
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<tbody>
<tr>
<td>Fee</td>
</tr>
</tbody>
</table>

#### K. Budget Justification*

- File Name: 1234-UofMbudgetjustification.pdf
- (Only attach one file.)

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**RESEARCH & RELATED Budget (F-K) (Funds Requested)**
### A. Senior/Key Person

<table>
<thead>
<tr>
<th>Prefix</th>
<th>First Name*</th>
<th>Middle Name</th>
<th>Last Name*</th>
<th>Suffix</th>
<th>Project Role*</th>
<th>Base Salary ($)</th>
<th>Calendar Months</th>
<th>Academic Months</th>
<th>Summer Months</th>
<th>Requested Salary ($)*</th>
<th>Fringe Benefits ($)*</th>
<th>Funds Requested ($)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(b) (6)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name: Total Senior/Key Person (b) (4)

### B. Other Personnel

<table>
<thead>
<tr>
<th>Number of Personnel*</th>
<th>Project Role*</th>
<th>Calendar Months</th>
<th>Academic Months</th>
<th>Summer Months</th>
<th>Requested Salary ($)*</th>
<th>Fringe Benefits*</th>
<th>Funds Requested ($)*</th>
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<tbody>
<tr>
<td>Post Doctoral Associates</td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Graduate Students</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Undergraduate Students</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Secretarial/Clerical</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 Research Coordinator</td>
<td>(b) (4)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1 Total Number Other Personnel

Total Other Personnel (b) (4)

Total Salary, Wages and Fringe Benefits (A+B)
**C. Equipment Description**

List items and dollar amount for each item exceeding $5,000

<table>
<thead>
<tr>
<th>Equipment Item</th>
<th>Funds Requested ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Total funds requested for all equipment listed in the attached file

Total Equipment

**Additional Equipment**

File Name:

**D. Travel**

1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)
2. Foreign Travel Costs

Total Travel Cost

(b) (4)

**E. Participant/Trainee Support Costs**

1. Tuition/Fees/Health Insurance
2. Stipends
3. Travel
4. Subsistence
5. Other:

<table>
<thead>
<tr>
<th>Number of Participants/Trainees</th>
<th>Total Participant Trainee Support Costs</th>
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</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**RESEARCH & RELATED Budget (C-E) (Funds Requested)**
**RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 5**

**ORGANIZATIONAL DUNS**: 5559179960000

**Budget Type**: ● Project  ○ Subaward/Consortium

**Organization**: Regents of the University of Minnesota

| Start Date* | 09-01-2018 |
| End Date*   | 08-31-2019 |

**Budget Period**: 5

**F. Other Direct Costs**

<table>
<thead>
<tr>
<th>Description</th>
<th>Funds Requested ($)</th>
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</thead>
<tbody>
<tr>
<td>1. Materials and Supplies</td>
<td>(b) (4)</td>
</tr>
<tr>
<td>2. Publication Costs</td>
<td>(b) (4)</td>
</tr>
<tr>
<td>3. Consultant Services</td>
<td>(b) (4)</td>
</tr>
<tr>
<td>4. ADP/Computer Services</td>
<td>(b) (4)</td>
</tr>
<tr>
<td>5. Subawards/Consortium/Contractual Costs</td>
<td>(b) (4)</td>
</tr>
<tr>
<td>6. Equipment or Facility Rental/User Fees</td>
<td>(b) (4)</td>
</tr>
<tr>
<td>7. Alterations and Renovations</td>
<td>(b) (4)</td>
</tr>
<tr>
<td>8. Duplication Costs/Transcription Services</td>
<td>(b) (4)</td>
</tr>
<tr>
<td>9. Biostatistical Data Analysis</td>
<td>(b) (4)</td>
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<tr>
<td>10. RESDAC Service</td>
<td>(b) (4)</td>
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</table>

**Total Other Direct Costs**

**G. Direct Costs**

<table>
<thead>
<tr>
<th>Funds Requested ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Direct Costs (A thru F)</td>
</tr>
</tbody>
</table>

**H. Indirect Costs**

<table>
<thead>
<tr>
<th>Indirect Cost Type</th>
<th>Indirect Cost Rate (%)</th>
<th>Indirect Cost Base ($)</th>
<th>Funds Requested ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>MDTC</td>
<td>(b) (4)</td>
<td>(b) (4)</td>
<td>(b) (4)</td>
</tr>
</tbody>
</table>

**Total Indirect Costs**

**Cognizant Federal Agency**

(Agency Name, POC Name, and POC Phone Number)

**I. Total Direct and Indirect Costs**

<table>
<thead>
<tr>
<th>Funds Requested ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Direct and Indirect Institutional Costs (G + H)</td>
</tr>
</tbody>
</table>

**J. Fee**

<table>
<thead>
<tr>
<th>Funds Requested ($)</th>
</tr>
</thead>
</table>

**K. Budget Justification**

File Name: 1234-UofMbudgetjustification.pdf

(Only attach one file.)

RESEARCH & RELATED Budget (F-K) (Funds Requested)
Personnel Justification

**Personnel**

Joseph E. Gaugler, PhD, Principal Investigator ([PI; 3 calendar months, Year 1; 4.2 calendar months Years 2 thru 4; 3.48 calendar months, Year 5]), will be responsible for successful conduct of the demonstration. Dr. Gaugler will administer the project, oversee the various data collection and management efforts of the research coordinator, identify and conduct semi-structured interviews with 30 participants at the completion of the randomized controlled evaluation (in collaboration with Dr. Garcia; please see below), and have primary responsibility for evaluating the eNeighbor remote sensor monitoring system for persons with Alzheimer’s disease or a related dementia (ADRD) and their family caregivers. The PI will also conduct initial visits to the homes of participating persons with ADRD to install eNeighbor and train family caregivers on the use of this remote monitoring system. The PI, in collaboration with The Lutheran Home Association, will oversee all system maintenance (battery changes, troubleshoot in instances where there is a loss of system contact), establish arrangements for other care services that are needed for the person with ADRD in instances of eNeighbor alerts or other health-related transitions, and develop and monitor a care plan with the family caregiver of the person with ADRD to ensure that it is effectively followed throughout the proposed project. Dr. Gaugler will also collaborate with the Community Advisory Board during quarterly meetings to facilitate the proposed demonstration and resulting dissemination efforts. Dr. Gaugler will conduct all quantitative data analyses in conjunction with the University of Minnesota Biostatistical Data Analysis Center (BDAC; see below) and will be responsible for the preparation of project reports, manuscripts, and other dissemination efforts. [Due to his various responsibilities on the proposed project and the increased effort required to implement and evaluate eNeighbor during Years 2-4, Dr. Gaugler will spend 3 calendar months in Year 1, 3.48 calendar months in Year 5, and 4.2 calendar months in Years 2-4.]
Other Costs

(b) (6)

(b) (4)
Organizational Chart

Joseph E. Gaugler, PhD
Principal Investigator
University of Minnesota

16-Member Community Advisory Board

Consultant
University of Washington

Consultant
University of Iowa

Co-Investigator
University of Minnesota

Co-Investigator
University of Minnesota

To be named
Research Coordinator
University of Minnesota

Biostatistical Support
University of Minnesota

Contact PD/PI: Gaugler, Joseph, K
(b) (6) (b) (6) (b) (6) (b) (6) (b) (6)
RESEARCH & RELATED BUDGET - Cumulative Budget

Totals ($)

Section A, Senior/Key Person
Section B, Other Personnel
Total Number Other Personnel
Total Salary, Wages and Fringe Benefits (A+B)
Section C, Equipment
Section D, Travel
  1. Domestic
  2. Foreign
Section E, Participant/Trainee Support Costs
  1. Tuition/Fees/Health Insurance
  2. Stipends
  3. Travel
  4. Subsistence
  5. Other
  6. Number of Participants/Trainees
Section F, Other Direct Costs
  1. Materials and Supplies
  2. Publication Costs
  3. Consultant Services
  4. ADP/Computer Services
  5. Subawards/Consortium/Contractual Costs
  6. Equipment or Facility Rental/User Fees
  7. Alterations and Renovations
  8. Other 1
  9. Other 2
  10. Other 3
Section G, Direct Costs (A thru F)
Section H, Indirect Costs
Section I, Total Direct and Indirect Costs (G + H)
Section J, Fee
### 1. Project Director / Principal Investigator (PD/PI)

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<thead>
<tr>
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<th>Dr.</th>
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<tbody>
<tr>
<td>First Name*:</td>
<td>Joseph</td>
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<td>Middle Name:</td>
<td>K</td>
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<tr>
<td>Last Name*:</td>
<td>Gaugler</td>
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<tr>
<td>Suffix:</td>
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### 2. Human Subjects

- **Clinical Trial?**
  - No
  - Yes

- **Agency-Defined Phase III Clinical Trial?**
  - No
  - Yes

### 3. Permission Statement*

If this application does not result in an award, is the Government permitted to disclose the title of your proposed project, and the name, address, telephone number and e-mail address of the official signing for the applicant organization, to organizations that may be interested in contacting you for further information (e.g., possible collaborations, investment)?

- Yes
- No

### 4. Program Income*

Is program income anticipated during the periods for which the grant support is requested?

- Yes
- No

If you checked "yes" above (indicating that program income is anticipated), then use the format below to reflect the amount and source(s). Otherwise, leave this section blank.

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### 5. Human Embryonic Stem Cells

Does the proposed project involve human embryonic stem cells?*  ● No  ○ Yes

If the proposed project involves human embryonic stem cells, list below the registration number of the specific cell line(s) from the following list: [http://grants.nih.gov/stem_cells/registry/current.htm](http://grants.nih.gov/stem_cells/registry/current.htm). Or, if a specific stem cell line cannot be referenced at this time, please check the box indicating that one from the registry will be used:

**Cell Line(s):** Specific stem cell line cannot be referenced at this time. One from the registry will be used.

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### 6. Inventions and Patents (For renewal applications only)

Inventions and Patents*: ○ Yes ○ No

If the answer is "Yes" then please answer the following:

Previously Reported*: ○ Yes ○ No

### 7. Change of Investigator / Change of Institution Questions

- Change of principal investigator / program director

Name of former principal investigator / program director:

Prefix: [ ]

First Name*: ...

Middle Name: ...

Last Name*: ...

Suffix: [ ]

- Change of Grantee Institution

Name of former institution*: ...

Tracking Number: GRANT11563457

Funding Opportunity Number: PA-13-046. Received Date: 2014-01-23T12:07:36.000-05:00
# PHS 398 Research Plan

Please attach applicable sections of the research plan, below.

<table>
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<td>Introduction to Application (for RESUBMISSION or REVISION only)</td>
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<td>2.</td>
<td>Specific Aims</td>
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<td>4.</td>
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<td>7.</td>
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<td>Vertebrate Animals</td>
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<td>Consortium/Contractual Arrangements</td>
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<td>Letters of Support</td>
<td>1255-LOS.pdf</td>
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<td>Appendix (if applicable)</td>
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Introduction

We thank you for the careful consideration of our proposal and the overall enthusiasm for the project. Below we summarize how we have addressed the reviewers’ comments. Updated text is in brackets ([ ]).

1. Evaluating the user interface of eNeighbor and its components/Quality of the attributes and the performance of the sensor system and portal. More detail is now provided on the utility and performance on the myHealthsense web-portal and other eNeighbor components. Specifically, we present additional descriptive research and case studies that demonstrate the utility and performance of the myHealthsense portal and the health monitoring sensor system. We also provide more detail on the feasibility of eNeighbor technology (as conducted by Dr. Kinney, a consultant on this project). The Appendix features more screenshots of the myHealthsense portal as well as the eNeighbor sensors. Taken together, these additions provide greater description of the ease of use and feasibility of the overall eNeighbor system.

2. Cost-effectiveness analysis. While space was constrained due to page limitations, we provided additional detail on the cost-effectiveness analysis. We attempted to revise the proposed cost-effectiveness analysis to avoid in overdrawn conclusions. In order to further discern whether potential delay or prevention of negative health transitions occur due to eNeighbor implementation or other factors, we will: a) examine the direct effect of treatment vs. control group assignment on residential care placement, hospitalization, and falls as suggested in our original analysis; and b) further explore potential interaction effects between treatment vs. control group assignment and other well-established predictors of residential care placement, hospitalization, and falls in dementia (e.g., client dementia severity, caregiver distress)\(^1\)\(^2\) to better elucidate the potential cost-effectiveness of eNeighbor.

3. Investigator effort. We have increased the effort of Dr. Westra (Co-Investigator) from .3 calendar months to 1.2 calendar months in all years. Dr. Garcia’s and Dr. Nyman’s (Co-Investigators) efforts were also increased to 1.2 calendar months in Years 3 through 5. The Co-Investigators’ respective efforts better reflect their responsibilities on the proposed project.

4. Community Advisory Board (CAB): Interface and Specific Aim 3. Space permitting, we have provided more detail in the Research Strategy as to how the CAB interfaces with the research team throughout the various phases of the proposed project. We also concur with the comment that the original Specific Aim 3 was “fuzzy;” to this end we removed it as an aim in the revised proposal. However, we continue to strongly emphasize stakeholder engagement throughout the project; it is now not a measurable “Aim” per se as it is more of an underlying methodology we will employ to ensure the utility of eNeighbor.

5. Organizational chart. An organizational chart is now included in the budget justification. Please note the CAB’s position; while the CAB will not have direct supervisory responsibilities over the project research team the CAB will play an advisory role in collaborative fashion with Dr. Gaugler throughout the proposed project.

6. Including those in independent living. We thank Reviewer 2 for this comment; our description in the Analysis Plan now notes that we will compare health monitoring technology’s efficacy in situations where the ADRD caregiver is living with the person with dementia or is living independently (see section C8c).

7. Including “how” in addition to “why” questions in the open-ended data collection elements. In both the treatment fidelity checklist and post-randomized control trial semi-structured interview guide, we now include “how” questions alongside the existing “why” queries to provide more extensive qualitative data for the mixed methods, embedded controlled evaluation.

8. Greater detail on budget justification. More detail is now provided on the costs requested to support the CAB and their travel to the University of Minnesota for consultation purposes, domestic and conference travel costs, and the eNeighbor technology. We have also removed reference to the “raffling” provision at the end of the proposed demonstration; instead, the equipment will be offered to the control group on a first-come, first-serve basis for free to use over an 18-month period to ensure rapport and retention. Reference to the research coordinator is also made consistent in both the budget pages and the justification.

9. Privacy concerns, only including caregivers in area. We apologize that privacy concerns were not addressed until the Protection of Human Subjects section; we now acknowledge the privacy controls of the health monitoring technology briefly in the Research Strategy (as space allowed). We also continue to maintain our focus on persons with ADRD and their family caregivers on the Minneapolis/St. Paul region as well as outlying rural areas in order to maximize the efficiency of the demonstration project and to facilitate the mixed methods data collection protocol.
Specific Aims

Coinciding with the growth of basic and clinical research on Alzheimer’s disease or a related dementia (ADRD), the study of family care for persons with ADRD has advanced considerably over the last three decades. A major emphasis of family caregiving research in ADRD has been the development and evaluation of various interventions to support families in need such as support groups, skills-based training, and psycho-therapeutic models. A limitation of many ADRD caregiver interventions is their crisis-driven orientation. For protocols that are based on consultation or similar clinical approaches, persons with ADRD or their family caregivers are often “treated” after the occurrence of a significant and negative health transition on the part of the person with ADRD (e.g., a wandering event, a behavioral outburst, a fall, etc.). This reactive model of care often extends to community-based services for persons with ADRD and their family caregivers. It is possible that the moderate or weaker benefits reported for many ADRD caregiver interventions are due to their crisis management orientation. Proactive approaches could allow families of persons with ADRD to more effectively manage the complex needs of cognitively impaired relatives.

One potential solution to effective symptom management in ADRD is health monitoring technology. The Lutheran Home Association, a non-profit long-term care company located in Belle Plaine, Minnesota, is a licensed provider of health monitoring technology (called “eNeighbor;” Healthsense, Inc.). The Lutheran Home Association (TLHA) has been implementing eNeighbor in residential long-term care environments and home settings in Minnesota and Wisconsin over the past 5 years. eNeighbor includes a combination of remote sensors that are safe, non-invasive, and located in the key areas of the person with ADRD’s home (e.g., bed, medicine cabinet or refrigerator doors, toilet, living rooms). Operating jointly, these sensors can immediately communicate any function that is outside of an expected performance threshold to the family caregiver as well as a care professional (e.g., a nurse care manager). The goal of the remote health monitoring technology is to prevent negative health transitions such as falls or wandering events, and thus provides a more proactive intervention model than standard clinical protocols for family caregivers of persons with ADRD.

In collaboration with a 16-member Community Advisory Board (CAB) that includes healthcare professionals and ADRD caregivers themselves, the proposed 5-year project will build on the current efforts of TLHA to evaluate eNeighbor remote monitoring technology for persons with ADRD living in the community and their family caregivers. [Specifically, we will engage stakeholders on a quarterly basis throughout the 5-year project to: a) review the study aims; b) provide feedback on the proposed mixed methods evaluation design, including sampling and data collection; c) review the analysis plan; d) assist the research team in interpreting qualitative and quantitative data; and e) facilitate the dissemination process. The overarching goal of engaging the CAB throughout the proposed demonstration project is to enhance the utility and relevance of eNeighbor for family caregivers of persons with ADRD.] The Specific Aims are as follows:

1) To determine the efficacy of remote sensor technology over an 18-month period for 100 persons with ADRD and their caregivers randomly assigned to an eNeighbor treatment condition when compared to 100 usual care controls. We hypothesize:
   - Hx. 1) Significant (p < .05) improvements in caregiver self-efficacy and sense of competence in managing a relative’s ADRD;
   - Hx. 2) Significant reductions in caregiver distress (e.g., subjective stress; depressive symptoms);
   - Hx. 3) Significant delay of or reductions in health transitions (falls, wandering) and service utilization (hospitalizations, nursing home admission) for persons with ADRD;
   - Hx. 4) Greater cost-effectiveness associated with a person with ADRD’s health service use; and
2) To determine why the health monitoring intervention was or was not efficacious. We will “embed” evaluation components: a) during the randomized controlled evaluation through the administration of open-ended survey items to all ADRD caregivers in the eNeighbor treatment condition every 6 months to examine the utility of the remote health monitoring technology; and b) at the conclusion of the 18-month evaluation by purposively sampling 15 ADRD caregivers who reported the greatest rate of decrease in subjective stress during their use of eNeighbor (i.e., those at the lowest quartile) and 15 ADRD caregivers who reported the greatest rate of increase in subjective stress (i.e., those at the highest quartile) to participate in semi-structured interviews.

Although the evidence base of dementia caregiver intervention efficacy has expanded, research that ascertains the potential of easy-to-use, acceptable technologies to facilitate care of persons with ADRD at home remains underdeveloped. The proposed project aims to fill this gap in scientific inquiry by engaging key stakeholders while evaluating a remote monitoring technology platform that adopts a more proactive intervention approach. We anticipate that the innovative health monitoring technology intervention will offer robust support for family caregivers of persons with ADRD in the community.
A. Significance

Alzheimer’s disease or a related dementia (ADRD) is extremely challenging to manage and treat due to complexities in detection, interacting symptoms, and length of progression. Because persons with dementia rely heavily on informal (i.e., unpaid) sources of care, the prevalence of Alzheimer’s disease (AD) has a staggering effect on families. In 2013, 80% of the 5.2 million persons with AD in the United States (U.S.) were cared for by a family member and 15.4 million individuals provided unpaid care to a person with ADRD. There is no one consistent definition of caregiving, but in its most global sense caregiving refers to attending to an individual’s health needs. More specific definitions emphasize that caregiving includes provision of assistance with one or more activities of daily living (such as bathing, dressing, transferring). In the dementia context, caregiving can extend to the management of symptoms such as memory loss, behavioral disruptions, and similar concerns. The typical AD caregiver in the U.S. is female, 48 years of age (suggesting multiple role responsibilities in addition to family care) and assists a relative who is 78 years old. A well-established literature demonstrates the adverse effects of ADRD care on family members including impaired physical health and immune system response, financial strain, financial strain, degradation in social well-being, and increased prevalence of negative mental health symptoms. With the accumulation of evidence demonstrating the physical, financial, social, and psychological risks of dementia family care, a series of clinical interventions have been developed and evaluated. Meta-analyses and systematic reviews suggest moderate overall benefits of these interventions for ADRD caregivers and their care recipients.

Although family members of persons with dementia are willing to utilize technology to improve their respective caregiving situations, few studies have determined whether various technologies can help families alleviate negative outcomes for caregivers of persons with ADRD. Among the potential benefits of technological interventions is the ability to assist family caregivers of persons with ADRD regardless of geographical distance, which is in contrast to standard ADRD caregiver interventions where treatment is often delivered face-to-face to family caregivers in need. Technology-based interventions also have the potential to overcome another barrier to ADRD caregiver interventions: that of time and scheduling. Family members can often utilize and benefit from various types of technology-based interventions at any time, thus making these approaches asynchronous. Technology interventions evaluated include telephone-based approaches (e.g., conference calls among family members of persons with ADRD) and computer or internet-based strategies (e.g., DVD-based delivery of education and support, online discussion boards). While technology interventions for ADRD caregivers have shown some promise, small samples, inconsistent measurement, and lack of high quality randomized controlled evaluations suggest the need for further research.

The proposed demonstration project will advance scientific knowledge, technical capability, and clinical practice as they pertain to ADRD caregiver interventions. Although research on family caregiving has served as a platform for multidisciplinary research, a critical gap in this literature is the lack of randomized controlled studies that evaluate advanced, low-cost, high potential technologies to alleviate the stressors and other negative outcomes associated with everyday ADRD care. The proposed project will be one of very few clinical trials that evaluate the efficacy of home-based sensor technologies on actual user outcomes (e.g., family caregivers, older adults) in a real world environment using an experimental design. Specifically, Healthsense, Inc. has developed a suite of remote monitoring tools called the eNeighbor, and the Lutheran Home Association (TLHA: a non-profit, long-term care provider) has been implementing eNeighbor in residential care settings and home environments in Minnesota and Wisconsin over the past 5 years. The objectives of eNeighbor are to lower the cost of care, increase independence of disabled older persons to “age in place,” and enhance quality of life for chronically disabled older persons and their family caregivers.

The home-based sensor technology of eNeighbor relies on multiple, non-invasive and safe remote monitors that can alert family caregivers and/or health professionals to potentially negative situations that lead to adverse outcomes (e.g., wandering, falls, incomplete activity of daily living tasks). The eNeighbor core system includes four unobtrusive motion sensors that are placed in a living room, bedroom, bathroom, and an entryway that can detect motion in a room to verify daily activity (and do not include a microphone or camera; see Appendix). These motion sensors operate jointly and exchange information to help identify significant changes in movement or function and can be used to detect urgent needs for help among persons with ADRD such as a fall. Three contact sensors can detect whether a door or cabinet is opened or closed; these sensors can measure whether the person with ADRD is accessing important areas of the home and can help to determine if basic care plans are followed or activities of daily living (ADLs) are performed as expected. A toilet sensor is also mounted inside a tank that can monitor flushes. A bed occupancy sensor is placed between the mattress and box spring that can monitor time in and out of bed for the person with ADRD, as such occupancy...
routines can help to detect potential early stage symptoms of a number of health conditions (e.g., night time rest is frequently interrupted due to pain).

Alerts are sent to the family caregiver as well as a nurse care manager that monitors the real-time information generated by the e Neighbor sensors. An example monitoring event could occur as follows: a motion sensor detects the person with ADRD has entered a bathroom. Once the person with ADRD enters the bathroom, the motion and toilet sensors’ timers are set at 10 minutes to determine whether any motion occurs in the bathroom or the toilet is wet or dry. If the motion or toilet sensors in the bathroom do not detect any activity within 10 minutes (or another household sensor detects activity in some other area of the home), an action alert is sent to notify the caregiver and nurse care manager that an expected ADL—using the bathroom—did not take place [(see the Appendix)]. e Neighbor sensors operate according to self-adapting thresholds (e.g., time expected to complete a given ADL) that can be set by the family caregiver or the nurse care manager upon installation of the system; if the person with ADRD is outside the normal timing threshold, the e Neighbor sensors will then alert the family caregiver and nurse care manager.

The technology platform of e Neighbor relies on wireless infrastructure that allows for remote monitoring via alerts that are communicated to the family caregiver’s or nurse care manager’s personal computers or handheld devices. e Neighbor also includes a private care coordination and socialization tool for the family caregiver of the person with ADRD through the MyHealthsense web portal. MyHealthsense provides scheduled reports to the family caregiver and the nurse care manager that summarizes e Neighbor sensor activity and links this information to the person with ADRD’s electronic health record. The MyHealthsense portal includes the nurse care manager involved in monitoring the e Neighbor sensor information, the ADRD family caregiver, and selected others in a “private health group.” Among the features of the MyHealthsense portal include the ability to enter personal and medical information for the person with ADRD through the MyHealthsense web portal. MyHealthsense provides personalized to older persons at-risk. The potential of health monitoring technology such as e Neighbor is also increased due to the lowered costs associated with sensors and sensor maintenance as well as more prevalent cellular and broadband connectivity in U.S. households. For these reasons, it is anticipated that health monitoring technology use will become more common in caregiving households.

B. Innovation

e Neighbor directly aligns with components of quality chronic disease care as proposed by healthcare experts and the Agency for Healthcare Research & Quality (AHRQ). e Neighbor and its integrated, remote sensor technology platform aims to prevent negative health transitions (i.e., falls, wandering) by allowing for a method of continuous monitoring and ongoing communication between the ADRD caregiver and a care manager. e Neighbor also allows for the appropriate management of chronic disease by episode instead of by health care professional encounter (e.g., regular visits to a primary care provider, emergency room visits), again resulting in a more proactive intervention approach. The remote monitoring platform of e Neighbor also allows chronic care to occur across locations as opposed to solely in formal medical settings. For these reasons, the e Neighbor intervention differentiates itself from many existing ADRD caregiver interventions which are often premised on crisis management (e.g., enacted only after a problem occurs).

This innovative dimension also becomes apparent when compared to other assistive devices, which do not provide person-centered, dynamic, time-sensitive information on older persons’ functional behaviors. Specifically, e Neighbor uses complex algorithms that allow for the identification of routine function of the older adult and whether behaviors occur within or outside expected thresholds to trigger further health intervention. Current assistive devices such as bed alarms provide some degree of monitoring assistance, but are more oriented around crisis management rather than prevention. Similarly, while assistive supports such as hand rails may offer the least expensive solution, they are not able to provide real-time, monitoring data that is personalized to older persons at-risk. The potential of health monitoring technology such as e Neighbor is also increased due to the lowered costs associated with sensors and sensor maintenance as well as more prevalent cellular and broadband connectivity in U.S. households. For these reasons, it is anticipated that health monitoring technology use will become more common in caregiving households.

Health care experts have emphasized the need to better utilize technology to enhance care management, track patient outcomes, and effectively administer treatments. While much is made of the promise of
Contact PD/PI: Gaugler, Joseph, K

primary objective stressors include could potentially alleviate negative outcomes. A final set of covariates considered in our conceptual model support and community-based service use are considered covariates in the eNeighbor conceptual model that could independently and directly: improve caregiver self-efficacy and competence, reduce caregiver distress (subjective stress and depressive symptoms), delay or reduce negative health transitions for the person with ADRD (falls, wandering), and delay or reduce the person with ADRD’s service utilization (residential care placement, hospitalization). The SPM is aligned with conceptualizations of intervention effectiveness in the health information technology literature, further suggesting its utility for the proposed demonstration.

B1. Novel Aspects and Advantage/Refinement over Existing Approaches

B1a. Conceptualization. The development and evaluation of the eNeighbor is grounded in a well-established conceptual model that has been used to successfully evaluate the efficacy of interventions for ADRD family caregivers: the Stress Process Model (SPM). The SPM is based on the mechanism of “proliferation,” where the emotional stress of care provision to a person with dementia (primary stress) spreads to other life domains which are then posited to negatively influence global caregiving outcomes such as caregiver mental health or the person with ADRD’s institutionalization. Psychosocial resources or formal service use may help stem stress proliferation and protect ADRD caregivers from negative outcomes.

The conceptual framework for the proposed project integrates constructs from the SPM. Context of care covariates include key sociodemographic and background characteristics that may influence outcomes for persons with ADRD or their family caregivers. Resource variables such as perceptions of socioemotional support and community-based service use are considered covariates in the eNeighbor conceptual model that could potentially alleviate negative outcomes. A final set of covariates considered in our conceptual model include primary objective stressors, or indices of dementia severity that may require greater day-to-day care provision on the part of family members. The proposed conceptual model positions eNeighbor as a key resource; the remote sensor technology of eNeighbor for dementia caregivers is hypothesized to independently and directly: improve caregiver self-efficacy and competence, reduce caregiver distress (subjective stress and depressive symptoms), delay or reduce negative health transitions for the person with ADRD (falls, wandering), and delay or reduce the person with ADRD’s service utilization (residential care placement, hospitalization). The SPM is aligned with conceptualizations of intervention effectiveness in the health information technology literature, further suggesting its utility for the proposed demonstration.

B1b. Methodology. Mixed methods include the collection, integration, and analysis of both quantitative and qualitative data. Among the various rationales for conducting mixed methods research are: a) to better understand a research problem by converging numeric trends from quantitative data and specific details from qualitative data; and b) to obtain...
statistical, quantitative data from a sample of a population and use them to identify individuals who may expand on the empirical results through qualitative findings. Few evaluations of ADRD caregiver interventions have combined qualitative and quantitative data to obtain a greater understanding of why certain protocols are beneficial or not. For these reasons, an embedded experimental mixed methods design will be utilized for the proposed demonstration. An embedded experimental mixed methods design combines the collection and analysis of qualitative data within a traditional randomized controlled trial (RCT) design; the collection of the embedded qualitative data may occur prior to, during, or after the RCT. The embedded experimental design will assist the research team examine the process of eNeighbor’s implementation during the conduct of the RCT and determine why and how the eNeighbor worked or did not for ADRD caregivers following the completion of the RCT (see Figure 1 above).

C. Approach

C1. Preliminary Studies

C1a. Research team expertise in ADRD caregiver interventions and health information technology. The Principal Investigator (PI), Joseph E. Gaugler, PhD, and colleagues enrolled 28 individuals who were caring for a co-resident family member with dementia (13 spouses, 15 adult children). [At baseline there were no statistical differences between health monitoring intervention and comparison group caregivers on most background variables. Follow-up assessments were conducted 20 weeks following baseline. Measures included caregivers’ rating and rank-ordering of the importance of 12 values. When compared to baseline, intervention group caregivers ranked meaningful activity and enjoyment as significantly more important than usual care controls at follow-up. Qualitative interviews were used to supplement and elaborate upon the quantitative findings; as one caregiver stated, “For the first few weeks I thought about it every time I opened something. I thought about it being recorded, but now I haven’t been thinking about it anymore.” This suggests that the technology may initially make caregivers hyper-vigilant; however, over time caregivers relax and let the technology’s vigilance substitute for their own. The importance of control also became more salient as caregivers came to trust the eNeighbor technology: “You had asked if we wanted a monitor on the front door and I said never, but then the other day he actually tried to get out the door. It happened to be locked and he couldn’t figure it out. I’ve never noticed that before. Now we want the monitor.”] Cumulatively, these preliminary studies suggest the increased sense of security eNeighbor offers to...
family caregivers and older adults, the potential of health monitoring technology to reduce costs related to health crises, and the feasibility of eNeighbor for ADRD caregivers.

[Additional support for the ease of use/interface with eNeighbor sensors and the myHealthsense web portal is evident in a descriptive study of the perceptions of 43 residents, family members, and staff using eNeighbor in a non-profit provider of community services, housing, and nursing homes (see Appendix).77 All residents surveyed agreed or strongly agreed that eNeighbor allowed them to live independently longer, that they felt safer when they were alone, and that the health monitoring system would get help for them if a negative health event occurred. All care providers strongly agreed or agreed that eNeighbor improved the quality of care to care recipients, helped them provide appropriate help to care recipients, and allowed them to better assess the care required by care recipients. TLHA has also trained other staff members to successfully use the sensors and myHealthsense portal; as noted by two care providers: Care provider 1: “Currently I (have)…an alert on the front door. I find the ability to disable this feature at times (via the myHealthsense portal) extremely useful. Also, having the capability to change the alert call and email lists has made it easy to add and remove (care providers) when someone is on vacation or new (care providers) begin working with the (care recipient)...the portal is user friendly, but I wish there was a way to easily remove ADLs that are no longer in use...The portal has been a great tool." Care provider 2: “I have no formal technical training, education or background and have never been particularly interested in technology until I started being involved in the use of the eNeighbor systems…I find the use of the sensors extremely simple. It usually only takes one short session of walking through the installation process with an individual and they are able to install them on their own…I can go into the portal and simply add that sensor to their home or apartment in just a few minutes and it is ready to go immediately…I use the portal on a daily basis and I find it easy to navigate…I have also taught many other staff and users in private homes in the community how to use it also…I use the portal to check on specific ADL activities and find it very easy to choose the activities and time period I want to include and run the report.”]

Ctc. Additional research infrastructure. Dr. Gaugler developed and maintains the University of Minnesota Caregiver Registry based on his various community outreach and education efforts on ADRD. All individuals in the Registry have provided permission for Dr. Gaugler and his research staff to contact them to participate in research. The Registry includes [449 dementia caregivers and 214 professionals as of 1/14/2014,] and calls for new Registry participants occur annually. These efforts will enhance the likelihood of meeting recruitment targets to conduct the proposed demonstration project.

C.2. Stakeholder Involvement

Where appropriate, we will adopt various strategies outlined by the AHRQ11 and others78 to engage stakeholders in an initiative to refine and enhance eNeighbor for family caregivers of persons with dementia. Following a broad invitation to the many community members and professionals the PI has served and collaborated with over the past 8 years, volunteer CAB members were identified (see Letters of Support). The 16-member CAB includes a geriatrician, a geriatric nurse practitioner and an experienced nurse care manager, an occupational therapist, and 2 social workers who provide psychosocial support, case management, or consultation to families of persons with ADRD. Six of the CAB members have spent multiple years providing care to relatives with memory loss themselves. Individuals on the CAB vary by gender, race/ethnicity, and their relative’s stage of dementia. [The CAB will review and consult on all aspects of planning and development and will also provide guidance to ensure that this demonstration project meets the needs of family caregivers, clinical care providers, and other professionals involved in the care for persons with memory loss. We believe this distribution of stakeholders creates a balanced array of viewpoints for advisory purposes. During its quarterly meetings (approximately 2 hours each) the CAB will review Specific Aim 1 and 2 progress. Each meeting will also include time to discuss concerns so that the CAB can propose mechanisms to resolve issues that arise during the mixed methods evaluation and demonstration.] The diverse professional and personal backgrounds of the CAB will help to strengthen the utility and feasibility of the eNeighbor and will ensure that the delivery and use of health monitoring technology appeals to a wide range of stakeholders. Members of the CAB were selected based on their day-to-day clinical and personal expertise in assisting families of persons with ADRD with the goal of having a diverse set of care disciplines represented. All participants of the CAB are within reasonable geographic proximity to the University of Minnesota and will be able to attend quarterly CAB meetings in-person in order to take advantage of high quality, interpersonal exchanges throughout the project (teleconferencing will also be available). As is evident in our letters of support, CAB members are aware of the general scope of the proposed project.

[The principal objectives of each CAB meeting will mirror the scope recommended by the AHRQ.11,78 Initial meetings will focus on the ethics and operating principles of each meeting, how collaborative partnerships will proceed, and relevant privacy and human subject issues as the demonstrate evolves. Subsequent meetings]
will focus on reviewing and, if necessary, refining the research questions of greatest interest to the stakeholder community regarding eNeighbor efficacy; the PI will then review the proposed research design and other key study procedures such as recruitment, health monitoring technology implementation, and measures and data collection with the CAB. Final meetings will focus on joint data interpretation and the ongoing role of the CAB in conceptualizing, drafting, and partnering in dissemination efforts (this would include a robust discussion of authorship) with an emphasis on maintaining the relevance of these findings to ADRD family caregivers and other stakeholders. The CAB will play a vibrant, stakeholder-centric role in this or any future effort that attempts to deliver health monitoring technology for family caregivers of persons with ADRD.11]

The philosophy underpinning the CAB meetings is one of balanced communication, mutual respect, and an interaction process where all viewpoints are heard and discussed openly. The PI will digitally record all meetings and interviews to provide an additional source of qualitative data on stakeholder perspectives. [Thematic analysis of these data (see C8e) will expand upon the mixed methods evaluation to more fully examine how health monitoring technology can be best designed for and delivered to ADRD caregivers.] Open sharing of meeting transcripts with all CAB members to review and edit will also occur to further establish a transparent environment. At the outset and throughout the course of the project, the CAB’s role as key collaborators on the embedded, mixed methods evaluation of eNeighbor will be emphasized. Barriers to stakeholder engagement will include some members of the CAB not feeling comfortable voicing their opinion alongside experienced clinical providers; in such instances we will seek these individuals out for additional individual interviews to solicit their opinions and perspectives. [Engagement with and participation of the CAB in this project will serve to engage key stakeholders from different organizations, care specialties, and communities to further position eNeighbor as a useful, person-centered technology for caregiving families.]

C3. eNeighbor Intervention Procedures

Following 200 ADRD caregivers’ enrollment into the proposed project and within 2 weeks of randomization to the eNeighbor treatment condition (n = 100; see below), the PI will schedule a visit at the home of the person with ADRD and the enrolled family caregiver. The PI will have received month-long training and certification from TLHA to provide health monitoring support to individuals who use the eNeighbor technology in community settings. The PI will oversee all system maintenance (battery changes, troubleshoot in instances where there is a loss of system contact), establish arrangements for other care services that are needed for the person with ADRD in instances of eNeighbor alerts or other health-related transitions, and develop and monitor a care plan with the family caregiver to ensure that it is effectively followed.

An initial needs assessment will take place to determine the best use and deployment of the eNeighbor remote sensor technology in the person with ADRD’s home (see Appendix). The assessment begins with an identification of risk factors that suggest the need for remote health monitoring (e.g., the person with ADRD lives alone and has little supervision; the caregiver needs support; the person with ADRD has a history of falls or the caregiver has concerns with falls) as well as the use of other monitoring systems such as Safe Return™ or a similar device. The PI will then discuss the results of the needs assessment with the ADRD caregiver and review how the remote monitoring system works, that the eNeighbor does not include cameras or microphones, is secure, and is private, and that the system learns the normal activities of the person with ADRD and alerts both the family caregiver and the PI if something appears unusual (e.g., absence of expected ADL behaviors). Following this operational overview, the PI will summarize [the secure and password-protected MyHealthsense website, which is used by the family caregiver or other trusted family members and friends to coordinate and share information regarding appointments or the well-being of the person with ADRD.] The remote monitoring system will then be installed in the person with ADRD’s home and the expected performance thresholds and daily routines will be programmed. The PI will monitor sensor performance throughout the duration of the project, and he will replace these sensors as needed for free.

A particularly important aspect of eNeighbor is its configuration in homes with varying broadband internet service. As of 2008 half of individuals from the ages of 50 and 64 had broadband access at home, with 19% of those 65 and older with such access. It is important to note that there is an annual growth rate in home broadband adoption of 26% since 2008.79 More recent surveys have found that 51% and 24% of adults 50-64 and 65 years of age and over own a laptop, respectively.80 If broadband services are available at the person with ADRD’s home, connection of the sensors involves the simple addition of a wireless router which connects with the existing broadband modem in the person with ADRD’s home (and is included in the remote sensor package). If broadband is not available, the current project will support connectivity for the person with ADRD’s home via purchase of this service as a “bundle” through an existing telephone or cable TV plan. In the instance the family caregiver does not wish to utilize broadband service options for the purposes of eNeighbor, the proposed project will support a low data rate cellular service plan that supports only eNeighbor functions. The
quality of data collection is identical across cellular or broadband modalities. The PI will then share paper versions of the alert system reports generated by the MyHealthsense website (see Appendix). As noted below, one of the key inclusion criteria for the proposed demonstration project is that family caregivers of persons with ADRD express a willingness to utilize the health monitoring technology; this will ameliorate issues related to resistance, technology literacy, and broadband accessibility.

Another key issue is the heterogeneity of persons’ with ADRD home environments. Unlike implementation in residential long-term care settings or housing units that may have similar environmental features, persons with ADRD in the community live in homes that range from apartment-style settings to domiciles with single or multiple floors. There are also various distances from principal bathrooms to the kitchen, living room areas, or entryway. To address this environmental diversity, the PI will collect information on the approximate square footage of the living area; number of bedrooms and bathrooms; distances between primary bathroom, living room area (e.g., where television or the majority of similar leisure activity takes place), and entryway; and number of levels in the home. This environmental diversity will then be integrated into the subsequent multi-level analysis (see below) to examine environmental variability and key outcomes.

The proposed project will include situations where family caregivers are co-residing with or living separately from the person with ADRD, as the remote monitoring system is capable of operation in either living arrangement. Specifically, the programming of individual routines and the personalization of the eNeighbor system for specific individuals allows the system to track and identify functional performance specifically for persons with ADRD. The algorithms of data collected by the sensors account for the movement and average activity level of multiple people in the home and the system will still issue an alert if there is a variation from the expected threshold. This serves as a trigger to check on multiple individuals to determine what condition caused the variation. Specific sensors are also positioned and assigned to the care recipient only and information gathered and automated alerts from these sensors are specific to the person with ADRD. Parameters for lack of activity and customized monitors can be adjusted for specific periods of time when the care recipient may be alone. In this manner, the eNeighbor system has the capability to identify routines for persons with ADRD if they are living alone or co-residing with a family caregiver.

C4. Eligibility Criteria

The following inclusion criteria will be applied for 200 persons with ADRD: 1) English speaking; 2) physician diagnosis of ADRD (Alzheimer’s disease, Lewy Body disease, fronto-temporal dementia, or stroke/vascular dementia; excluding mild cognitive impairment only); 3) not currently receiving care or case management services; and 4) 65 years of age and over (as Medicare and Medicaid claims data for these individuals will be available for the proposed cost-effectiveness analysis; see below). Caregivers of persons with ADRD must: 1) speak English; 2) be 21 years of age and over; 3) self-identify as someone who provides help to the person with ADRD because of their cognitive impairments; 4) self-identify as the person most responsible for providing care to the person with ADRD; 5) plan to remain in the area for at least 18 months in order to reduce possible loss to follow-up; and 6) indicate a willingness to use eNeighbor.

C5. Enrollment, Recruitment, and Randomization Procedures (Months 3-34)

The PI will initiate email, telephone, or mail contact with ADRD caregivers on the University of Minnesota Caregiver Registry or others recruited for the project. In addition, the PI will ask professional caregivers on the Registry to identify ADRD caregivers for recruitment purposes. During initial enrollment contacts, the PI will describe the eNeighbor monitoring system, explain study procedures, and invite potential ADRD caregivers to participate. Caregivers will be offered the opportunity to ask any questions about the study procedures. If caregivers agree to participate, the PI will initiate a brief screening procedure applying the inclusion criteria above. Baseline interviews will then be scheduled within 2 weeks for eligible caregivers. In addition to securing signed consent of primary caregivers, verbal assent of persons with ADRD will take place. For those individuals who receive a score of 20 or above on the brief St. Louis University Mental Status examination (SLUMS; moderate/mild cognitive impairment), verbal assent to continue with the research procedures will be collected. If a person with ADRD scores below 20 on the SLUMS, only consent of the caregiver will take place. Following the completion of baseline interviews, ADRD caregivers will be randomly assigned to an eNeighbor treatment condition that receives the multi-sensor, remote monitoring system or an attention control group. Randomization (participant is assigned to either the treatment or control condition) will be completed via an a priori list generated from http://randomizer.org by the PI. The PI will inform the ADRD caregiver of their randomization status within 2-3 days following completion of the baseline interview.

In addition to general recruitment assistance, the PI will ask professional care providers in the Registry (many of whom provide care to under-represented older persons) to identify ADRD caregivers of diverse ethnic
or racial origin and geographic location to enhance the inclusion of AHRQ Priority Populations. These recruitment efforts will be facilitated by the Minnesota Board on Aging (MBA) and the Minnesota-North Dakota Alzheimer’s Association regional office (see Letters of Support). For example, the MBA will help us promote this study through Area Agencies on Aging, many of which serve ethnic and racially diverse older adults as well as rural ADRD caregivers. Cumulatively, these various outreach efforts are expected to result in a sample that includes approximately 40 diverse and under-represented ADRD caregivers (20% of the sample).

C5a. Attention control group. The attention control group will adjust for the social engagement provided to the eNeighbor treatment condition. The PI or research coordinator will provide quarterly contact calls and a biannual project newsletter to all participants. Based on our prior experience, ADRD caregivers in an attention control group will often seek information and psychosocial support during quarterly contact calls; in order to balance ethics with the integrity of the randomized control design, the research team will provide free information resources (e.g., brochures from the Alzheimer’s Association). The PI or research coordinator will collect data on the duration, frequency, and content of each quarterly contact call. This approach is similar to those we have designed for previous ADRD caregiver randomized controlled trials (R01 AG022066).

C5b. Participant accrual and attrition. The recruitment approach described above will be initiated in Month 3 of the proposed project and will continue to Month 34. Follow-up will continue until Month 53, resulting in 51 months of data collection. Eligible ADRD caregivers will be interviewed at baseline and every 6 months thereafter for up to 18 months. A 1.5 year follow-up period was selected because a minimum of 18 months is often needed in order to detect changes in several of the selected outcomes, such as delayed nursing home admission. Based on a 20% refusal rate among eligible caregivers in the Registry and the anticipated number of ADRD caregivers that our professional collaborators will likely identify (factoring a 20% refusal rate and recruitment of at least one ADRD caregiver per professional), we have confidence that the proposed project will achieve the sample target of 200 caregivers.

Based on our previous ADRD caregiver intervention work at the University of Minnesota that featured low loss to follow-up (approximately 3% over a 2- to 3-year follow-up period; AG022066), we will take several steps to address attrition bias. If a person with ADRD has moved into a residential long-term care facility or has died, caregiver follow-up interviews will include queries determining when these events occurred. Regular follow-up will continue with a modified protocol in order to collect as much information on outcome variables that are appropriate (i.e., intention to treat principle). In instances where ADRD caregivers wish to withdraw from the study we will determine the reason for study withdrawal, and if the caregiver agrees we will administer regular, brief surveys (either online or over the telephone) to collect data on outcome variables. For cases that are lost to follow-up and 6-, 12-, or 18-month data are unavailable, an event history analysis (such as a Cox proportional hazards model) will be utilized to examine predictors of time until exit. Loss to follow-up will also be addressed via the implementation of a multi-level analytic strategy that can include participants with missing panel data when estimating outcome trajectories or other parameters (see below).

Several steps will enhance retention in the proposed study, many of which were successfully implemented by the PI in prior ADRD caregiver intervention research (AG022066). Baseline and follow-up interviews will take place at a location and in a format that is convenient to ADRD caregivers (at the University of Minnesota Delaware Clinical Research Unit, the ADRD caregivers’ home or through online, telephone or mail formats if desired). Each interview is anticipated to take no more than 45-60 minutes to complete. The research coordinator or PI will complete confirmation calls or emails 1-4 days prior to a scheduled interview, will contact ADRD caregivers within 24 hours of a missed interview to reschedule, and will update participants’ contact information as needed throughout the project. Birthday cards as well as a bi-annual project newsletter will also be sent to all participants to provide updates on study progress as well as provide seasonal caregiving tips. In order to maintain rapport and follow-up in the control condition, controls will be offered free use of the eNeighbor technology sensors that were previously used by the treatment participants at the conclusion of the randomized controlled trial for a 1.5 year period.

C6. Experimental Data Collection Procedures (Specific Aim 1; Months 3-53)

All interviews will be completed by the PI or research coordinator. The selected measures (see Appendix) have strong psychometric properties, sensitivity to change, and clinical relevance as established in stress process and health information technology conceptual models. Caregivers will complete measures at each time point (context of care items will be collected at baseline only). All scaled measures will be summed.

Context of care. Context of care variables include geographic location (based on Beale codes: http://www.ers.usda.gov/briefing/rurality/ruralurbcn/), time since diagnosis, Medicaid status, living arrangement of the person with ADRD, and caregiver and person with ADRD demographics. As noted above, environmental characteristics will be collected by the PI during the home assessment for participants in the
eNeighbor treatment condition.

**Primary objective stressors.** Primary objective stressors will include the person with ADRD’s dependence on assistance with 6 activity of daily living (ADL) tasks and 6 instrumental activity of daily living (IADL) tasks as well as whether there is an unmet need for help in completing each activity.\(^{56,57,58,89}\) An 8-item scale will assess the intensity of relatives’ memory losses, communication deficits, and recognition failures at each time point (memory impairment).\(^{58,59}\) The frequency of behavior problems in the person with ADRD will be measured with the Revised Memory and Behavior Problems Checklist (R-MBPC), which consists of a list of 30 common behavior problems in ADRD.\(^{90}\) Type of dementia diagnosis will also be included.

**Resources.** Socioemotional support will be measured on a 5-item scale to assess the affective assistance provided to the caregiver by relatives or friends at each time point.\(^{58,59}\) Primary caregivers will be asked to identify, from a fixed list of options, community-based or health services they have used in the past 6 months and how often they relied on these services.\(^{91}\) Caregivers will also be asked whether they currently use Safe Return™ or similar assistive devices for the person with ADRD and their duration of use. Caregivers’ own functional dependency will be assessed by the ADL and IADL measures described above.

**Caregiver self-efficacy and sense of competence.** An 8-item measure of caregiver self-efficacy will be utilized.\(^{92,95}\) Caregivers’ sense of competence will be measured with the 7-item Short Sense of Competence Questionnaire (SSCQ) to assess sense of capability in providing assistance to a relative with ADRD.\(^{94-96}\)

**Caregiver distress.** The 22-item Zarit Burden Interview, one of the most widely-used measures of caregiver subjective stress, will be included.\(^{97,98}\) Two additional indices of subjective stress will be utilized:\(^{58,59}\) a 4-item scale assessing the involuntary aspects of the caregiving role (role captivity) and a 3-item scale measuring caregivers’ feelings of emotional and physical fatigue (role overload). The 20-item Center for Epidemiological Studies-Depression scale will be used to measure caregiver depressive symptoms.\(^{99,100}\)

**Person with ADRD negative health transitions and service utilization.** Caregivers will assess the frequency of falls and wandering that have occurred for persons with ADRD. The well-researched assessment approach developed by Tinetti and colleagues will be utilized; a fall will refer to “an unintentional change in position to the floor or ground” by the person with ADRD.\(^{101}\) ADRD caregivers will also be asked how often the person with ADRD “wandered or got lost.”\(^{102}\) Both fall and wandering events will utilize the same Likert scaling approach as the validated R-MBPC when determining frequency. The frequency of residential care placement (entry into a 24-hour type of residential care setting for at least 90 days such as a nursing home, assisted living, or similar residential setting), overnight hospitalization, and emergency room use occurred will be collected via caregiver report at each interview. Prior efforts have demonstrated acceptable agreement between caregiver reports of service use with other methods (i.e., claims data).\(^{91}\)

**C7. Embedded Procedures (Months 9-55)**

**C7a. Treatment fidelity/Process evaluation (Months 8-55).** The first embedded component of the mixed methods evaluation design will determine how eNeighbor is utilized by persons with ADRD and their family caregivers. A particular focus of this component is acceptability; since many ADRD caregivers have never used eNeighbor or a similar health monitoring technology before, it will be important to assess the ease of use of the eNeighbor via various open-ended and close-ended data elements.\(^{103,104}\) A strength of eNeighbor is its inherent standardization; its physical presentation is the same for all participants. For these reasons, the intervention “protocol” per se is already standardized and ensures that the mode of treatment delivery is the same for each caregiver. Monthly system reviews will take place through system reports generated by the PI; as noted above the eNeighbor system collects and maintains alerts and other information generated by the networked sensors. The MyHealthsense portal will also track how often the ADRD caregiver or others utilize the [various care coordination resources and tools’ of MyHealthsense.

The PI or research coordinator will also determine the degree to which participants apply the eNeighbor monitoring tool to their everyday care situations. An online or mail survey of close-ended, Likert-scale items to determine eNeighbor’s acceptability by ADRD caregivers as well as multiple open-ended questions will be administered to all ADRD caregivers in the eNeighbor treatment condition at the 6-, 12-, and 18-month interview intervals (see Appendix). The open-ended responses will provide qualitative data as to the reasons why family caregivers felt the health monitoring technology of eNeighbor was or was not easy to utilize (e.g., “Why or how was the health monitoring technology easy or difficult to use?” see Appendix for full listing of items). The identification of these barriers or facilitators will be considered when examining ADRD caregivers’ perceptions of eNeighbor’s design, delivery, and ease of use.

**C7b. Post-evaluation semi-structured interviews (Months 54-55).** The second embedded component of the proposed mixed methods evaluation will include 30 semi-structured interviews with ADRD caregivers in the e-Neighbor treatment condition. These interviews will take place a month after completion of the final 18-month
follow-up interview. A sequential mixed methods sampling approach will be utilized where the results of the first methodological strand (the eNeighbor RCT) will inform the selection of participants in the second methodological strand (the proposed semi-structured interview protocol). Specifically, the PI and Dr. Garcia (the Co-I) will identify 15 ADRD caregivers who reported the greatest rate of increase in subjective stress during their 6-month use of eNeighbor (i.e., those at the highest quartile of overall increases on the Zarit Burden Interview) and 15 ADRD caregivers who reported the greatest rate of decrease of subjective stress over the 18-month study period (i.e., those at the lowest quartile of overall decreases on the Zarit Burden Interview). A stratified purposive sampling approach will also be applied; the PI and Dr. Garcia will purposively identify ADRD caregivers of varying kin relationship (spouse vs. adult child), dementia severity (middle versus late stage dementia symptomatology), caregiver gender, and racial or ethnic background to participate.

The open-ended responses of the semi-structured interviews will provide in-depth information on the reasons why dementia caregivers felt the eNeighbor remote sensor technology did or did not reduce ADRD caregivers’ distress, help to manage persons’ with ADRD daily function, or prevent negative health transitions and service use for persons with ADRD (see Appendix for the interview guide). The PI and research coordinator will schedule and conduct the semi-structured interviews and will digitally record each interview. Audio recordings will be transcribed by a professional transcriptionist into a Microsoft Word file which will then be uploaded to nVivo 10 for subsequent analysis (see below). This mixed methods design will thus allow the research team to link the efficacy results of the RCT to the themes derived from the semi-structured interviews.

C8. Analysis Plan and Considerations (Months 55-60)

C8a. Determination of sample size. Intensive longitudinal analysis procedures (growth curve modeling) will be utilized to capitalize on the randomized design and the multiple waves of data that will be collected. The number of ADRD caregivers to be enrolled to address Hypotheses 1-3 was determined using power analysis procedures that take into account the hierarchical analytic design of the study. In this framework, the researcher identifies the Type I error rate (e.g., p < .05) to differentiate between a null and alternative test hypothesis, a suitable level of statistical power (.80 is considered an excellent power value), and the expected difference between the two study groups in order to determine the number of ADRD caregivers to enroll into the project. We sought a sample size that would be sufficient to detect a group difference of 0.50 standard deviation units. This is considered to be a “medium” effect size and is a reasonable benchmark to evaluate the efficacy of a new behavioral intervention in comparison to an attention control condition. Using these specifications, a sample size of 200 ADRD caregivers (factoring in the anticipated 3% attrition rate) was found sufficient. As noted by expert qualitative methodologists, a sample of 30 is considered an adequate sample size for semi-structured interview protocols to ensure the richness of open-ended data collected.

C8b. Analysis of Specific Aim1: Tests of Hypotheses 1-3. Data available at baseline, 6 months, 12 months, and 18 months will allow for individual growth curve models that examine change in ADRD caregiver outcomes. Multilevel analysis approaches are available that support growth curve modeling. In this context, growth curve modeling is an example of a 2-stage modeling process consisting of 1) a within-subjects model across time; and 2) a between-subjects model that incorporates caregiver and person with ADRD covariates. The primary independent variable in the proposed investigation consists of an indicator variable for random assignment into the eNeighbor treatment condition or the attention care control. IBM SPSS Statistics will be used to conduct these analyses, as it supports multilevel and growth curve modeling procedures. Dr. Gaugler, the PI, has extensive experience conducting longitudinal and growth curve analyses in his prior research on ADRD caregiving.

Our proposed analyses will provide in-depth tests of Hypotheses 1 thru 3 (i.e., rates of change in ADRD caregivers’ self-efficacy, competence, subjective stress, depressive symptoms, and frequency of negative health transitions and service use). In one set of outcome evaluations, the baseline value will be included as a covariate and time will be “centered” at 6-months post-baseline. This scales the intercept effect to be a main effect of eNeighbor group assignment and allows the eNeighbor treatment and the attention control groups to have different 6-, 12-, and 18-month change trajectories, or an expanded eNeighbor treatment*time interaction effect. After establishing that the individual growth parameter estimates have significant variance around the mean trajectories of change in key dependent variables, an eNeighbor treatment vs. attention care control group indicator will be added as the key independent variable to predict intercepts and rates of change in outcomes. Additional analyses will determine if covariates (e.g., stress process model covariates including context of care indicators, primary objective stressors, and resources) significantly vary across the eNeighbor treatment and attention control groups at baseline and over time via growth curve modeling procedures. If statistically significant variations between the eNeighbor treatment and control groups are found, initial status and rate of change parameters for these covariates will be included to provide additional statistical control.
Cox proportional hazard survival analyses will determine whether participation in the eNeighbor treatment group results in significantly less time to nursing home admission (e.g., admission into a 24-hour nursing facility for at least 90 days), overnight hospitalization, emergency room use, and negative health transitions (falls, wandering) when compared to persons with ADRD in the attention control group (Specific Aim 1/Hypothesis 3). The Cox proportional hazards model is defined as the product of an unknown function of time and the exponent of a linear combination of risk variables. eNeighbor treatment vs. attention control group membership will be the independent variable of interest in the test of Hypothesis 3; time to nursing home admission, overnight hospitalization, emergency room use, and occurrence of a fall or a wandering event will serve as the dependent variables. Date of randomization will serve as baseline. Additional variables will serve as covariates, including time-invariant and time-varying measurements of stress process covariates. Likelihood ratio tests and partial odds ratios will be examined in order to determine the degree to which these variables explain the observed effects of eNeighbor on time to dependent variable occurrence.

C8c. Variations in eNeighbor use and setting. Empirical treatment fidelity data and context of care measures that assess heterogeneity in the use of eNeighbor (e.g., frequency and duration of sensor alerts and myHealthsense website use; diverse home characteristics) will be included as a series of secondary Specific Aim 1 analyses. [We will also compare eNeighbor’s efficacy in situations where the ADRD caregiver is living with the person with dementia or in instances where the person with dementia is living independently. As we anticipate most caregiving situations will include co-residence, we will attempt to recruit a subsample of at least 40 independently-living care recipients in order to determine variations in efficacy based on living arrangement.] These secondary analyses will explore the effects of variations in eNeighbor use on the outcomes hypothesized for persons with ADRD and their family caregivers.

C8d. Specific Aim 1/Hypothesis 4. The cost-effectiveness of the remote monitoring technology intervention will be assessed by comparing costs of implementation and healthcare utilization between persons with ADRD in the treatment condition and those in the attention control. The analysis will be conducted from the perspective of the payer (i.e., the public). Costs in the numerator of the incremental cost-effectiveness ratio (ICER) will be determined by identifying the differences in Medicare and Medicaid expenditures for persons with ADRD across the eNeighbor treatment and attention control groups using aggregated (“rolled up”) Medicare and Medicaid claims matched to the individual participant by Social Security number for the 18 months of participation. Because the differences in costs derive from a randomized trial, an evaluation of the difference in mean costs can determine significance. In addition, the direct costs of the intervention will be included as the cost of the remote sensor hardware, staff time (i.e., the PI will track his hourly effort related to monitoring eNeighbor activities and assisting ADRD caregivers over a 1.5-year period), and installation costs over the 18-month study period.

The differences in effectiveness included in the denominator of the ICER will be measured using 7 ADRD caregiver and person with ADRD outcome measures: a) the standard cut-point of “moderate or higher” burden on the Zarit Burden Interview;\textsuperscript{113} b) the standard cut-point of “major depression” on the Center for Epidemiological Studies Depression scale;\textsuperscript{114} c) fall (occurred or not); d) wandering event (occurred or not); e) nursing home admission (placed or not); f) hospitalization (overnight use or not); and g) emergency room use (used or not). Significant differences in cost will be investigated. Sensitivity analysis will be performed where parameter uncertainty exists. Where possible, evaluation of these ICERs will be based on comparisons in prior literature to determine the overall costs and effectiveness of eNeighbor.

[In order to further discern whether potential delay or prevention of negative health events due to eNeighbor use or other factors, we will explore potential interaction effects between treatment vs. control group assignment and other well-established predictors of residential care placement, hospitalization, and the other negative health events listed above (e.g., client dementia severity, caregiver distress).\textsuperscript{1,2} In addition to our proposed cost-effectiveness analysis examining the direct effects of eNeighbor on dementia caregiving outcomes, inclusion of interactions will elucidate the complex process of negative health transitions in the RCT and the attending cost implications of potentially delaying these costly transitions. In addition, including additional explanatory variables to account for greater variability will increase the efficiency of the estimator on the intervention variable.]

C8e. Analysis: Specific Aim 2. Specific Aim 2 analyses will primarily focus on thematic content analysis of open-ended data from [surveys, interviews, and CAB meetings] to examine eNeighbor utility and mechanisms of benefit. As noted by experienced methodologists, systematic reading and rereading of qualitative content and hand coding of a significant proportion of this content is necessary in order to develop an understanding of meanings in their conversational or observational contexts.\textsuperscript{115,116} Specifically, the PI and research coordinator with the help of Dr. Garcia (Co-Investigator) will independently develop coding coding categories together with
descriptors (via hand-coding and NVivo) and will generate a shared coding scheme that will reflect the primary
categories of the transcription. Through repetition of this procedure, a consensus perspective on appropriate
coding categories and themes will be modified and developed. These themes will provide insights as to the
eNeighbor’s implementation and use (i.e., treatment fidelity/process evaluation embedded component) and
mechanisms of benefit (i.e., semi-structured interview embedded component).

Grounded theory techniques described by Morse\textsuperscript{117} and Strauss and Corbin\textsuperscript{115} will guide the analyses of
qualitative data. These approaches allow participants to construct meanings, perceptions, and behaviors from
their own vantage points. All open-ended data collected will be first read by the PI and the research coordinator
to identify textual elements that emerge repeatedly (i.e., codes); these codes will then be clustered into larger
categories that are later used to construct major thematic elements from the text (with the use of nVivo 10
analytic software). During monthly meetings in the analysis phase of the proposed project, the PI and research
coordinator along with Dr. Garcia will discuss their own identified codes to reach a consensus about specific
codes, categories, and themes that emerge from the qualitative data (these decisions will be noted in an audit
trail). In addition, patterns that link particular themes will be identified and discussed in successive meetings
between the PI, research coordinator, and Dr. Garcia to identify more complex processes of eNeighbor use or
health monitoring technology’s pathways to benefit for persons with ADRD and their family caregivers.

Additional mixed methods analyses\textsuperscript{66,67} will take place. The thematic codes and categories of
implementation/use and mechanisms of benefit will be cross-tabulated with the empirical data from the
randomized controlled evaluation to determine whether the findings diverge, converge, or highlight pathways
toward additional questions and analysis.\textsuperscript{66} This comparative, mixed method analysis approach may suggest
that those who reported greater decreases in subjective stress during health monitoring technology use may
indicate certain themes more often than ADRD caregivers who report greater increases in stress.

C9. Dissemination

The Resource Sharing Plan provides comprehensive details of the various dissemination efforts
anticipated. Members of the CAB will be invited to co-author or first author these dissemination efforts to
enhance stakeholder engagement and promote dissemination efforts across a wide variety of platforms (e.g.,
blogs). The involvement, leadership, and editorial roles of the research team (see Resource Sharing Plan) will
facilitate the dissemination of our project findings in various professional conferences, webinars, society web
sites, and scientific or professional journals. In addition, since many members of the CAB have links to local,
state, and federal organizations that represent a wide range of disciplines, the CAB will be engaged in the final
months of the project to identify organizations that may wish to receive presentations, publications, or other
resources related to eNeighbor development. CAB members will be encouraged to take the lead in any
presentations or publications related to this outreach effort. Dr. Gaugler and the CAB will also consult with the
Office of Discovery and Translation (ODAT; part of the University of Minnesota Clinical and Translational
Science Institute) with the goal of utilizing various communication tools (e.g., blogs, social media, Wikipedia or
other similar tools) to disseminate the findings generated from the various Specific Aim procedures.

C10. Project Timeline

<table>
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<tr>
<th></th>
<th>Months 1-3</th>
<th>Months 4-12</th>
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<tr>
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<tr>
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<tr>
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</tr>
<tr>
<td>Quantitative, qualitative, and mixed analysis</td>
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<td>●</td>
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<tr>
<td>Dissemination</td>
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</tr>
</tbody>
</table>

NOTE: ADRD = Alzheimer’s disease or a related dementia; RCT = randomized controlled trial; ● = primary focus; ○ = ongoing but less intensive
Protection of Human Participants

Risks to the Participants

Human participant involvement and characteristics. Participants in this study will include 200 family caregivers of persons suffering from Alzheimer’s disease or a related dementia (ADRD). Dementia caregivers will be recruited from the University of Minnesota Caregiver Registry maintained by Dr. Gaugler (the Principal Investigator/PI) and community organizations. An additional 16 Community Advisory Board (CAB) members will consult with the research team on the progress of the proposed demonstration, utility of the health monitoring technology, and dissemination. The age range of all participants is expected to be from 30 to 70.

Sources of data and materials. Data will be derived from in-person interviews with ADRD caregivers (an online, telephone, or mail survey option will be offered to interested caregivers). Additional open-ended data will be collected during quarterly CAB meetings and follow-up interviews (the latter if needed). The Principal Investigator (PI) and research coordinator will be responsible for all data collection procedures.

Potential risks. The study involves no invasive procedures and there will be no physical risks to study participants. The consideration of need is potentially stressful, and thus there are possible psychological risks for the caregiver. Since the research team has considerable experience providing psychosocial support to ADRD caregivers on various research protocols, serious psychological risks are unlikely to occur. The potential social or legal risks for the participants relate only to possible violations of confidentiality. Given the procedures outlined below, such risks are highly unlikely. There may be instances where health monitoring could potentially reduce family caregiver vigilance; the regular communication between the PI and family caregivers regarding the functional activity of the person with ADRD should help to avoid this potential risk.

With respect to private information entered into the online portal of the eNeighbor myHealthsense site, the design of the system includes a structure of permissions with password protection to limit access to material so only ADRD caregivers, invited family members or health care professionals, and the research staff (the PI or research coordinator) can view sensitive information.

Adequacy of Protection against Risks

Recruitment and informed consent/Protection of risk. In creating our research design and sampling procedures, an important objective was to preserve the privacy, confidentiality, and autonomy of all participants. Beginning in Month 3 the PI will identify family caregivers from the University of Minnesota Caregiver Registry who would potentially benefit from eNeighbor. The following inclusion criteria will be applied for persons with ADRD: 1) English speaking; 2) physician diagnosis of ADRD (e.g., Alzheimer’s disease, Lewy Body disease, fronto-temporal dementia, or stroke/vascular dementia; not mild cognitive impairment); 3) not currently receiving care or case management services; and 4) 65 years of age and over (as Medicare claims data for these individuals will be available for the proposed cost-effectiveness analysis; see below). Caregivers of persons with ADRD must: 1) speak English; 2) be 21 years of age and over; 3) self-identify as someone who provides help to the person with ADRD because of their cognitive impairments; 4) self-identify as the person most responsible for providing care to the person with ADRD (i.e., the “primary” family caregiver; which can include highly involved kin or non-kin of persons with ADRD); 5) plan to remain in the area for at least 18 months in order to reduce possible loss to follow-up; and 6) indicate a willingness and need to use eNeighbor.

Given our extensive research on dementia caregiving populations as well as the general literature, it is unlikely primary caregivers will be under the age of 30; therefore, we do not anticipate requiring additional consent mechanisms or protections of risk for individuals under the age of 21. The PI will describe the study process to an eligible caregiver and will provide an Institutional Review Board-approved consent form to sign. The client base of the University of Minnesota Caregiver Registry is largely Caucasian (approximately 92%), which is similar to the state of Minnesota (see http://www.aoa.gov/AoARoot/Aging_Statistics/Census_Population/census2010/Index.aspx). For these reasons, any non-Caucasian caregivers from the Registry will be approached by the PI to participate in the randomized controlled evaluation. We will also ask professional care providers in the Registry to help us recruit dementia caregivers of diverse ethnic/racial origin or geographical location to improve the heterogeneity of the sample. In addition to securing signed consent of caregivers, verbal assent of persons with ADRD will take place. If caregivers agree to participate, the PI will initiate a brief screening procedure applying the inclusion criteria above. In addition to securing signed consent of primary caregivers, verbal assent of persons with ADRD will take place. Specifically, for those individuals who receive a score of 20 or above on the brief St. Louis University Mental Status examination (SLUMS; moderate/mild severity of impairment),81 verbal assent to continue with the research procedures will be collected. If a person with ADRD scores below 20 on the SLUMS, only consent of the caregiver will take place. As noted in the Research Strategy, 30 ADRD caregivers in the eNeighbor treatment condition will be purposively sampled by kin relationship, gender, person with...
ARDR dementia severity, and race/ethnicity to participate in semi-structured interviews (conducted by the PI or research coordinator at the conclusion of the evaluation) to collect more in-depth information on why eNeighbor was or was not beneficial.

Quarterly CAB meetings will be digitally recorded and transcribed. Transcriptions will be circulated to the CAB for review prior to each meeting, and the narrative information from these meetings will be coded for themes related to eNeighbor utility.

All interviews will be conducted by either the PI or research coordinator. These interviews will be either in-person or over the telephone. An online or mail survey option will also be available if the ADRD caregiver prefers. The PI will conduct all baseline interviews and the PI or research coordinator will conduct interviews with caregivers every 6 months over an 18-month follow-up period as well as semi-structured interviews with 30 ADRD caregivers in the treatment condition following completion of the randomized controlled trial. Interviews will continue to be administered whether the person with ADRD is at home or enters a residential long-term care setting. A specially modified protocol that collects appropriate post-placement or post-bereavement data will occur for caregivers of persons with ADRD who enter a residential long-term care setting or die during the course of the study. In this manner, a minimum of 4 waves of quantitative data (baseline/prior to intervention, 6-, 12-, 18-month intervals) will be available to participants who are not lost to follow-up.

During the informed consent process, the PI will explain the project in detail to each potential participant, including a description of the types of assessments to be obtained and the time required. The participant will read the study consent and/or assent form and will have the opportunity to ask questions prior to signing the form. The participant may take the consent form home to review and ask questions of the investigators at a time that is convenient to them. The consent form will also be reviewed and signed by the PI.

Additional protection against risks. As indicated above, the experience of the research team will minimize the possibility of psychological risks. The unlikelihood of such problems is evident from the absence of any clinically significant problems during the past 8 years that the research team has operated various protocols related to dementia caregiving research. The research coordinator will be trained to interview in ways that are non-threatening, friendly, and respectful. We will emphasize to all participants that they do not have to complete any questions they do not want to answer, and that the interview may be terminated at any time according to their wishes. We will stress to ADRD caregivers that their decision to discontinue the study will in no way affect the services they are receiving from the University of Minnesota or other entities.

In the event a caregiver does become upset during the interview process, the research coordinator will contact Dr. Gaugler who will be available for consultation. If a caregiver is in crisis because of their care situation or some other reason, the research coordinator will be instructed to consult with Dr. Gaugler. With the caregiver’s permission, we will then contact the appropriate resource person in an external agency (e.g., the Alzheimer’s Association). Based on the research team’s experience working with caregiving families, we expect no or very few such instances to occur. If a member of the research team does identify neglect or other potentially inappropriate care practices, the state Ombudsman will be notified to protect the rights of persons with dementia and their families.

All information obtained from participants will remain strictly confidential and will not be released except at the express written request of the study participant. All electronic data will be maintained on Dr. Gaugler’s office computer and the School of Nursing shared project folder. Per University of Minnesota and the Academic Health Center-Information Systems data security guidelines, all data on Dr. Gaugler’s computer in 6-153 Weaver-Densford Hall and the research staff’s computers (located in 120 Dinnaken Office Building) are encrypted and protected by strong password only accessible to Dr. Gaugler or the research team. Project data will be maintained on Dr. Gaugler’s research team’s computers and on the School of Nursing secure shared servers for approximately 2-3 years which is the time necessary to disseminate all research papers or presentations from these data. Similarly, paper forms of the data will be located in a locked file cabinet in 120 Dinnaken Office Building (Dr. Gaugler’s research office) only accessible to the research team. Unless the data are being filed or accessed, these cabinets will remain locked.

Per Center for Medicare & Medicaid Services data transfer standards, Medicare and Medicaid health service utilization and cost data can be linked to individual research participants in this study, but outside of the research team all participant data that are analyzed or disseminated will remain confidential using the data security procedures outlined above. As summarized in the consent and assent process, we will ask persons with ADRD (if they are screened as having mild or moderate severity of impairment on the SLUMS; see above) and their caregivers for permission to utilize the care recipient’s CMS data for the purposes of this research project.
Potential Benefits of the Proposed Research to the Participants and Others
We believe participation in the eNeighbor evaluation will yield benefits for participants. Utilization of the eNeighbor remote sensor technology will provide ADRD caregivers with the ability to identify and monitor changes in activities of daily living that may prevent negative health transitions and unwarranted service use on the part of persons with ADRD, and thus result in reduced distress for ADRD caregivers.

Importance of the Knowledge to be Gained
Although the evidence base of dementia caregiver intervention efficacy has expanded, studies that evaluate the efficacy of assistive technologies to facilitate families’ care of relatives with ADRD are underdeveloped. The proposed project aims to fill this scientific and clinical gap by evaluating a remote monitoring technology platform that adopts a more proactive intervention approach. We anticipate that the eNeighbor intervention will offer robust support for family caregivers of persons with ADRD in the community.

Data Monitoring and Safety Plan
A data monitoring safety plan (DMSP) that includes a data safety and monitoring officer is proposed to provide additional oversight of the research protocol and adverse event reporting, if necessary. The main activities of the DMSP will be as follows (taken from National Institute of Allergy and Infectious Diseases guidelines):

1. Review of interim and cumulative data for any evidence of study-related adverse events (AEs);
2. Review of interim/cumulative data for evidence of efficacy of the intervention;
3. Review of data quality, completeness, and timeliness;
4. Review the adequacy of compliance with goals for recruitment and retention, including those related to the participation of women and minorities;
5. Review adherence to the protocol;
6. Review factors that might affect the study outcome or compromise the confidentiality of the data (such as protocol violations, unmasking, etc.); and
7. Identification of factors external to the study such as scientific or therapeutic developments that may impact participant safety or the ethics of the study.

Prior to University of Minnesota Institutional Review Board (IRB) submission, Dr. Gaugler will identify a Data Monitoring Officer (DMO) at the University of Minnesota School of Nursing. The DMO will be a senior faculty member with experience conducting clinical trials. An independent expert in geriatrics (there are several at the University of Minnesota) will also be identified and invited to review our data monitoring protocol and reports.

Review process. Dr. Gaugler, the DMO, and the geriatrician will review data monitoring and safety activities annually during the 5-year project period. The responsibility of Dr. Gaugler (who also has oversight for the data management and analysis of the project) will include the production of an administrative report that will highlight study accrual. In addition, Dr. Gaugler will provide information on any deviations from the approved protocol (e.g., deviations in adhering to study eligibility criteria), error rates, and any other issues related to the progress of the study. The DMO and geriatrician will review the administrative report to ensure ongoing quality control, and will work with Dr. Gaugler if necessary to identify individual cases to ascertain any deviations in the approved study protocol. Following this review, the administrative report will be presented to the Agency for Healthcare Research & Quality (AHRQ). In instances of adverse events (see below), the DMO, the geriatrician, the AHRQ project officer, and the University of Minnesota IRB will be notified immediately.

The administrative reports will include the following:
1. Table of contents
2. Narrative/trial summary
   a. Summary of main findings
   b. Discussion of issues or problems
   c. Report preparation procedures
3. Study description
   a. Project organizational chart, personnel
   b. Brief statement of purpose of trial
   c. Projected timetable and schedule
4. Study administration
   a. Recruitment and participant status
      i. Table 1: Enrollment by year or month of study
      ii. Figure 1: Comparison of target to actual enrollment by month
b. Forms status
   i. Status of forms (e.g., consent, completing of screener, baseline assessment battery, etc.)

Safety reports. In addition to producing administrative reports on an annual basis to the DMO and geriatrician, Dr. Gaugler will generate annual safety reports that will list adverse events, serious events, unexpected events, events related to or associated with the intervention, and the potential causality of the intervention to the event for each participant. Taken from the September 2002 National Institutes of Mental Health policy on Data and Safety Monitoring in Clinical Trials, the definition of each event is as follows:

Adverse event. Any untoward medical occurrence in a patient or clinical investigation participant which does not necessarily have to have a causal relationship with the treatment. An adverse event can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding, for example), symptom, or disease temporally associated with the use of [an intervention], whether or not considered related to the [interventions].

Serious adverse event. Any adverse experience that results in any of the following outcomes: death, a life threatening experience, inpatient hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life threatening, or require hospitalization may be considered a serious adverse experience when based upon appropriate medical judgment, and they may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

Unexpected. Any adverse experience, the specificity or severity of which is not consistent with the risk information described in the [protocol or consent documents].

Related to (or associated with) the intervention. There is a reasonable possibility that the experience may have been caused by the intervention.

Causality. A reasonable possibility that the product is etiologically related to the adverse event. Causality assessment includes, for example, assessment of temporal relationships, dechallenge/rechallenge information, association with (or lack of association with) underlying disease, presence (or absence) of a more likely cause, plausibility, etc.

In the instance of an adverse event, Dr. Gaugler will classify whether the event is unexpected, adverse, or seriously adverse, whether the event is unexpected or related to the intervention, and what potentially caused the event. Dr. Gaugler will review the data routinely and will alert the DMO, the geriatrician and AHRQ if these events occur. Dr. Gaugler will present the safety report to the DMO and geriatrician to ensure that there are no negative effects of the treatment.

The DMO and geriatrician will review the safety reports annually to ensure that the proper procedure was followed and to identify any potential trends in the data. Dr. Gaugler will present the safety reports to AHRQ if adverse events occur.

Data report. Dr. Gaugler will also prepare interim analysis reports for review with the DMO and geriatrician. These interim analysis reports will include the following:

1. Recruitment and participant status
   a. Table 2: Targeted/Planned Enrollment Table
   b. Table 3: Demographic and key baseline characteristics by group

2. Safety assessment for all participants
   a. Table 4: Treatment duration for all participants
   b. Table 5: Treatment duration for participants who discontinue eNeighbor®
   c. Table 6: Adverse events by participant
   d. Table 9: Serious adverse events by participant
   e. Table 10: Participant deaths

Reports from the DMO (largely taken from National Institute of Allergy and Infectious Diseases guidelines). At the conclusion of each annual review, the DMO will discuss her/his recommendations and findings with Dr. Gaugler. If necessary, the DMO will also issue a written summary report that identifies key issues in the administrative, safety, and data reports and provides overall safety assessment and recommendations. Any rationale for recommendations will be included where appropriate. The report will not include confidential information. Following dissemination of this report to Dr. Gaugler, Dr. Gaugler will provide the report to AHRQ and the Co-Investigators for review.

The DMO and geriatrician will notify Dr. Gaugler of any findings of a serious nature or recommendations to discontinue all or part of the intervention. Dr. Gaugler will then immediately inform the project officer at AHRQ of this recommendation.
Relationships between the proposed data monitoring and safety plan and the IRB. We will notify the University of Minnesota IRB of our data monitoring and safety plan. If the University of Minnesota IRB requests it, we will provide feedback to the IRB of these data monitoring activities on an annual basis (in addition to the annual progress reported required by the University of Minnesota IRB). A brief summary report will be sent to the IRB documenting that a review of the data took place on a given date and will outline the DMO’s review of any adverse or unanticipated events. Any requests for modification in the protocol will also be forwarded to the University of Minnesota’s IRB.
Inclusion of Women and Minorities

Consistent with other samples reported in the dementia caregiving literature, we anticipate the majority of family caregivers of persons with Alzheimer’s disease or a related dementia (ADRD) will be women (estimated at 80%). Due to the ethnic and racial distribution of older adults in the state of Minnesota (http://www.aoa.gov/AoARoot/Aging_Statistics/Census_Population/census2010/Index.aspx) and increased efforts to identify and recruit caregivers of racial/ethnic minority status in this proposal, we anticipate that approximately 20% of our sample will be non-Caucasian. During the recruitment procedures Dr. Gaugler (the Principal Investigator) will identify dementia caregivers in the University of Minnesota Caregiver Registry via targeted recruitment and outreach to aid in increasing the number of eNeighbor users who are of diverse ethnic or racial origin and meet Agency for Healthcare Research & Quality (AHRQ) priority population criteria. We will also ask professional care providers in the Registry, many of whom provide care to under-represented older persons (e.g., individuals of racial or ethnic minority status; individuals in rural regions), to help us recruit ADRD caregivers of diverse ethnic or racial origin and geographic location. We have also reached out to the Minnesota Board on Aging (MBA) and the Alzheimer’s Association to support the proposed project (see Letters of Support). The MBA will help us promote this demonstration project through Area Agencies on Aging, many of which serve ethnic and racially diverse older adults (e.g., the Metropolitan Area Agency on Aging) as well rural ADRD caregivers (e.g., Area Agencies on Aging that serve older adults residing outside of the 7 county Minneapolis/St. Paul area). The Alzheimer’s Association will list our project on their TrialMatch site (http://www.alz.org/research/clinical_trials/find_clinical_trials_trialmatch.asp) to reach out to potential ADRD caregivers. To further facilitate these efforts, Dr. Gaugler will conduct a number of free community presentations on memory loss and the eNeighbor remote sensor system throughout the Minneapolis/St. Paul area and outlying rural regions to recruit under-represented individuals to participate in the eNeighbor evaluation. Dr. Gaugler has conducted similar presentations in almost every region in Minnesota over the past 8 years, and he has successfully used these efforts to recruit ADRD caregivers for past projects. Cumulatively, these various outreach efforts are expected to result in a sample that is more diverse than the Minnesota elder population is as a whole and adequately represents AHRQ priority populations.
# Planned Enrollment Report

**Study Title:**
A Proactive Health Monitoring Intervention for Dementia Caregivers: The eNeighbor

**Domestic/Foreign:**
Domestic

**Comments:**
200 family caregivers of persons with Alzheimer's disease or related dementia.

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Study 1 of 1
Inclusion of Children

Since this research topic is not relevant to children, individuals under the age of 21 will not be included. In both the Principal Investigator’s multiple descriptive and intervention studies of family caregivers of persons with Alzheimer’s disease or a related dementia and the general literature, “primary” caregivers (or those who assume the most responsibility for assisting a cognitively impaired relative) are rarely under the age of 30.
Bibliography and References Cited


34. Rentz M, Hoene AV. Online coaching for caregivers: Using technology to provide support and information. *Alzheimers Care Today.* 2010;11:206-209.


References Cited


1. George Demiris, PhD, FACMI, Alumni Endowed Professor in Nursing, School of Nursing & Professor of Biomedical Informatics and Medical Education, School of Medicine, Director, Clinical Informatics and Patient Centered Technologies, Graduate Program Director, Biomedical and Health Informatics, University of Washington
2. Kathleen C. Buckwalter, PhD, RN, FAAN, Professor Emerita, College of Nursing, University of Iowa, Professor of Research & Distinguished Nurse Scientist in Aging, Donald W. Reynolds Center of Geriatric Nursing Excellence, Oklahoma University Health Sciences Center
3. Jennifer M. Kinney, Ph.D., Professor of Gerontology, Department of Sociology and Gerontology, Miami University
4. Michael R. Klatt, President and Chief Executive Officer, The Lutheran Home Association
5. Jean K. Wood, Executive Director, Minnesota Board on Aging
6. Heidi Haley-Franklin, MSW, LICSW, Associate Program Director, Clinical Services, Alzheimer's Association: Minnesota-North Dakota Regional Office
7. Philippe Gaillard, PhD, Research Associate, Biostatistical Design and Analysis Center, Clinical and Translational Science Institute, University of Minnesota
8. Connie White Delaney, PhD, RN, FAAN, FACMI, School of Nursing Professor & Dean; Academic Health Center Director, Biomedical Health Informatics; Associate Director-Biomedical Informatics Core; Acting Director of the Institute for Health Informatics
9. Community Advisory Board Letters of Support:
   a. Venoreen Browne-Boatswain, Caregiver, Minneapolis, MN
   b. Kirsten Cruikshank, MSW, LGSW, Community Partners, Two Harbors at Home/Block Nurse Program, Two Harbors, MN
   c. Deborah Delaney, Founder/CEO, Flagship Franchises of MN, Inc., Touching Lives Adult Day Services, Touching Lives Communities, Savage, MN
   d. Kathleen Dempsey, RN, BC, Pathfinder Care Management, Minneapolis, MN
   e. Karen Gallagher, LISW, St. Louis Park, MN
   f. Heidi Haley-Franklin, MSW, LICSW, Associate Program Director, Clinical Services, Alzheimer's Association: Minnesota-North Dakota Regional Office, Edina, MN
   g. Kate Knapp, Caregiver, Minneapolis, MN 55414
   h. Danielle Lesmeister, RN, Director of Housing and Homecare, Skyview/Suncrest/MRP III, Morris MN
   i. Siobhan McMahon, PhD, MPH, GNP-BC, Assistant Professor, School of Nursing, University of Minnesota, Minneapolis, MN
   j. A. Richard Olson, Caregiver and Board of Trustees Ecumen Inc., Board of Directors Mill City Commons, Minneapolis, MN
   k. James T. Pacala, MD, MS, Distinguished Teaching Professor and Associate Head Department of Family Medicine and Community Health, University of Minnesota Medical School, Minneapolis, MN
   l. Patricia Schaber PhD, OTR/L, Associate Professor, Program in Occupational Therapy, University of Minnesota, Minneapolis, MN
   m. Kathleen Schaefer, Caregiver and PhD, LP
   n. Francis Scheve, Caregiver, Golden, CO
   o. Paul V. Snyder, MSW, MDiv, Caregiver and Manager, Minnesota Partnership for School Connectedness (MPSC), Social Work Faculty, Leadership Education in Adolescent Health (LEAH) Fellowship Program, Adjunct Faculty, University of Minnesota School of Social Work, Konopka Institute for Best Practices in Adolescent Health, Minneapolis, MN
   p. Donna Walberg, Owner, Work Smart, Inc., and Alzheimer's Care Partner, St. Cloud, MN
January 20, 2014

Joseph E. Gaugler, Ph.D.
Associate Professor, McKnight Presidential Fellow
Editor-in-Chief, Journal of Applied Gerontology
School of Nursing, Center on Aging
University of Minnesota

Dear Dr. Gaugler:

I am happy to serve as a project consultant for your innovative AHRQ R18 effort to evaluate the efficacy of health monitoring technology for persons with dementia and their family caregivers. I believe the proposed demonstration project will go far in examining alternative means to support families of persons with dementia. I have a long history of conducting research as PI and Co-I with older adults and technology (e.g., R01NR012213, R01NR011472, NSF-CDI-1028195). My research interests (which are represented in 152 peer-reviewed publications) include e-health and home-based patient-centered technologies, such as the use of telehealth to bridge geographic distance and improve health care delivery and education for older adults and patients with chronic conditions. I am currently the PI of an NINR R01 project (NR012213) that will test interventions for family caregivers of hospice patients that are delivered through telehealth, and an NSF CDI grant (CEDI1028195) that examines environmental home based sensors to assess mobility. My interests in and experience with "smart home" applications will directly facilitate the implementation, evaluation, and analysis of how and why eNeighbor benefits persons with ADRD and their family caregivers.

I acknowledge that my effort will be 30 hours of consulting time each year at a rate of $100 per hour in Years 1-3 ($3,000 total per year) and 50 hours of consulting time in Years 4 and 5 ($5,000 total per year).

Thank you for inviting me to serve as a Consultant on this project, and I look forward to this collaboration.

Sincerely,

George Demiris, PhD, FACMI
Alumni Endowed Professor in Nursing, School of Nursing &
Professor of Biomedical Informatics and Medical Education, School of Medicine
Director, Clinical Informatics and Patient Centered Technologies
Graduate Program Director, Biomedical and Health Informatics
University of Washington
BNHS-Box 357266
Seattle, WA 98195-7266
January 20, 2014

Joseph E. Gaugler, PhD  
Associate Professor  
McKnight Presidential Fellow Editor-in-Chief  
*Journal of Applied Gerontology*  
School of Nursing  
Center on Aging  
University of Minnesota,  
Minneapolis, MN

Dear Dr. Gaugler:

I am excited to serve as a project consultant for your innovative AHRQ R18 effort to evaluate the efficacy of health monitoring technology for persons with dementia and their family caregivers. This project is a technological advance in providing support to caregivers of persons suffering from dementia, and its orientation around preventing health crises is an important contribution.

I have a long history of conducting research in geropsychiatric nursing, particularly interventions for behavioral and psychological symptoms in persons with dementia and their formal (long-term care staff) and family caregivers (R01 NR03234, NIA/Rural Aging Center; Administration on Aging, NIMH; Alzheimer's Association, Division of Nursing, DHHS; NINR F33 award, all as PI). My expertise in dementia caregiving interventions will help to frame the conceptual, clinical, and scientific implications of this project within a geriatric nursing perspective. In particular, I will assist you in monitoring the progress of recruitment, integrity of random allocation, treatment fidelity of the health monitoring technology, and interpretation of the qualitative and quantitative data to be collected from the embedded experimental evaluation. I will also assist you to facilitate the dissemination of the evaluation results to appropriate scientific and clinical venues.

I acknowledge that my effort will be 30 hours of consulting time each year at a rate of $100 per hour in Years 1-3 ($3,000 total per year) and 50 hours of consulting time in Years 4 and 5 ($5,000 total per year).

I look forward to working with you and your staff on this exciting project!

Sincerely,

Kathleen C. Buckwalter, PhD, RN, FAAN  
Professor Emerita, College of Nursing  
Professor of Research & Distinguished Nurse Scientist in Aging  
Donald W. Reynolds Center of Geriatric Nursing Excellence  
Oklahoma University Health Sciences Center
January 7, 2014

Joseph E. Gaugler, Ph.D.
Associate Professor, McKnight Presidential Fellow
Editor-in-Chief, Journal of Applied Gerontology
School of Nursing, Center on Aging
University of Minnesota
6-153 Weaver-Densford Hall, 1331
308 Harvard Street S.E.
Minneapolis, MN  55455

Dear Dr. Gaugler,

I am very pleased to serve as a project consultant for your innovative AHRQ R18 effort to evaluate the efficacy of health monitoring technology for persons with dementia and their family caregivers. This project is a technological advance in providing support to caregivers of persons suffering from dementia, and its orientation around preventing health crises is an important contribution. As you know, I have conducted preliminary work in this area and can provide consultation as to the implementation and evaluation of the proposed project, which includes an NIH-funded study of health technology and dementia caregiving. Clearly, information on the benefits of easy-to-use, non-invasive, community-based health technologies for persons with dementia and their caregivers is lacking, and this effort will greatly advance our understanding of how to utilize health monitoring technology for these families in need.

I acknowledge that my effort will be 30 hours of consulting time each year at a rate of $100 per hour in Years 1-3 ($3,000 total per year) and 50 hours of consulting time in Years 4 and 5 ($5,000 total per year).

Again, I look forward to working with you and your staff on this important effort.

Sincerely,

Jennifer M. Kinney, Ph.D.
Professor of Gerontology and Interim Chair;
Research Fellow, Scripps Gerontology Center
January 7, 2014

Joseph E. Gaugler, Ph.D.
The University of Minnesota
6-153 Weaver-Densford Hall, 1331
308 Harvard Street SE
Minneapolis, MN 55455

Dear Dr. Gaugler,

This letter is in support of your application and our proposed partnership to evaluate the eNeighbor remote monitoring technology for persons with ADRD and their family caregivers.

The Lutheran Home Association enthusiastically supports your research proposal submission to the Agency for Healthcare Research and Quality to evaluate home health monitoring technology for persons with dementia and their family caregivers. The Lutheran Home Association (TLHA) has rapidly deployed advanced health monitoring technology that is serving to provide cost effective, yet advanced, solutions to the long term care challenges many older adults face. This proven technology care model that TLHA has developed over the past 5 years consists of advanced health monitoring and emergency response technology paired with innovative services. As a direct result of this technology care model, successful outcomes for older adults with multiple chronic conditions, such as Alzheimer's include; improved health, greater independence and better care at a significantly lower cost.

The Lutheran Home Association has implemented innovative health monitoring technology systems with over 100 older adults in assisted living, memory care and independent apartment homes. In addition, TLHA installs and monitors health monitoring technology in private homes and low income housing developments. TLHA secured a $500,000 grant through the Minnesota Department of Human Services to implement health monitoring technology in seven Minnesota rural counties to serve frail/at risk older adults. TLHA was recently featured on the front page of the Minneapolis Star Tribune highlighting the positive impact that health monitoring technology provides for older adults.

TLHA maintains extensive experience in aging and disability service development and health monitoring technology implementation. The Lutheran Home Association will assist Dr. Gaugler in providing installation expertise, technical assistance, and care management guidance throughout the duration of Dr. Gaugler's evaluation.
You have spent much of your career examining the longitudinal implications of informal long-term care, the effectiveness of community-based and psychosocial interventions, and the social integration of older persons in residential long term care. Most recently, your work has sought to examine the use of everyday technologies and information to enhance and improve the experience of families caring for and experiencing chronic illness, most notably Alzheimer’s disease. For these reasons, The Lutheran Home Association is committed as an active partner with you in support of this project and our collaborative efforts in attempting to further the area of innovative health system development and technology services. We believe that this project has significant potential to provide innovative solutions that assist informal caregivers in assessing and managing symptoms in individuals with Alzheimer’s disease.

We look forward to working with you in collaboration on various technical, programmatic and clinical aspects of the project. Please do not hesitate to contact me if you have any questions or would like additional information."

Caring about the Care of the Soul,

Michael R. Klatt
President and Chief Executive Officer
January 7, 2014

Joseph E. Gaugler, Ph.D.
Associate Professor, McKnight Presidential Fellow
Editor-in-Chief, Journal of Applied Gerontology
School of Nursing, Center on Aging
University of Minnesota
6-153 Weaver-Densford Hall, 1331
308 Harvard Street S.E.
Minneapolis, MN  55455

Dear Dr. Gaugler:

I am writing on behalf of the Minnesota Board on Aging (MBA) in support of your proposal, to the Agency for Healthcare Research & Quality to evaluate the eNeighbor remote monitoring technology for family caregivers in Minnesota.

The MBA is a 25-member, Governor-appointed board that is the designated state unit on aging. It promotes policies to the State Legislature, the Governor and State Agencies that fairly reflect the needs and interests of the older Minnesotans. In addition, the MBA provides objective information and promotes public education on ways to meet the changing needs of Minnesota's older population to age well and live well. The MBA administers and oversees the effective use of Older Americans Act and state funds to support older Minnesotans by Area Agencies on Aging and other service providers who will also play a key role on your project.

Minnesota now ranks second among the states in life expectancy at birth: 78.82 years (behind Hawaii at 80.0). Longer life expectancy in Minnesota coupled with a small net in-migration of persons age 85 and older who return to Minnesota after living their younger retirement years in another state contribute to increasing the number and proportion of the “oldest old.” The challenges for caregivers will only grow.

Persons aged 85 and older have a significantly higher prevalence of chronic illness and rates of disability. While Minnesota's disability rates are below the national average, the overall need for long-term care will increase because functional disability increases with advancing age - despite the lower rate at which this occurs. Over two-thirds of persons age 85 and older have at least one disability, and older persons are more likely to have several chronic conditions, each of which poses a challenge to the individual's ability to function independently. This presents particular challenges to caregivers.
The MBA is a strong supporter of evidence-based practices in Minnesota communities for persons with chronic illnesses and their family caregivers. It has received several grants from the Administration on Aging to support various initiatives with the Area Agency on Aging network including translating the NYUCI, consumer-directed initiatives for older persons, and a number of other projects that you have been involved in.

The MBA would be happy to assist you in identifying Area Agencies on Aging and staff within those agencies to help you identify underserved family caregivers of persons with Alzheimer's disease or related dementias. We think these individuals would benefit greatly from the eNeighbor remote monitoring system. Specifically, we will connect you with staff in the Metropolitan Area Agency on Aging and rural Area Agencies on Aging to identify feasible recruitment approaches and opportunities in the community (e.g., dissemination of study flyers, community presentation opportunities, local care providers) to help improve your recruitment and accrual of underserved family caregivers.

If you have any questions, please feel free to contact me at 651-431-2563 or jean.wood@state.mn.us.

Sincerely,

Jean K. Wood
Executive Director
January 7, 2014

Joseph E. Gaugler, Ph.D.
Associate Professor, McKnight Presidential Fellow
Center on Aging, School of Nursing
Coordinator of Research Initiatives, Center for Gerontological Nursing
University of Minnesota
6-153 Weaver-Densford Hall, 1331
308 Harvard Street S.E.
Minneapolis, MN 55455

Dear Dr. Gaugler/Joe,

The Alzheimer’s Association Minnesota North Dakota chapter is excited to support your proposal submission to the Agency for Healthcare Research and Quality to evaluate home health monitoring technology for persons with dementia and their family caregivers. We believe strongly that the remote sensory technology that you are planning to evaluate could yield an exciting, innovative model to support persons with Alzheimer’s disease and a related dementia as well as their family caregivers.

As you know, the Alzheimer’s Association Minnesota North Dakota chapter has provided services, information and advocacy for 30 years to persons with dementia, their families and health care providers. We have had a long history of collaboration, and we see this as the next logical step in your research and in our joint interests. We certainly can help you promote your project, particularly underserved families (ethnically and racially diverse or rural families) via TrialMatch®, an Alzheimer’s Association web-based service that connects individuals living with dementia and their caregivers to research studies across the country. We believe that TrialMatch® would provide a valuable participant recruitment tool for your study. We will also share recruitment information through our network as appropriate and feasible.

We look forward to working with you on this exciting project!

Sincerely,

Heidi Haley-Franklin, LICSW

Heidi Haley-Franklin, MSW, LICSW
Director of Clinical Services
Alzheimer’s Association Minnesota-North Dakota
7900 West 78th Street, Suite 100
Minneapolis, MN 55439
p 952.857.0527
f 952.830.0513
hhaleyfranklin@alz.org
Minneapolis, MN

January 7th, 2014

Dear Dr. Gaugler,

This letter is to support your proposal submission to the Agency for Healthcare Research and Quality to evaluate home health monitoring technology for persons with dementia and their family caregivers. I enthusiastically support your efforts to evaluate how this emerging technology can be put to ideal use to offer additional support to family caregivers of persons with Alzheimer's disease or a related dementia. In particular, I plan to provide biostatistical support to your project in Year 5.

Since May 2007, I have worked as a statistical consultant within the University of Minnesota – Academic Health Center, and I have enjoyed collaborating with you on several research projects.

For this E-Neighbor study, I plan on contributing to the research design, statistical analysis, and interpretation of results. I will be conducting the necessary statistical computations using SAS 9.4 for Windows.

I look forward to helping you complete this research project.

Philippe R. Gaillard, Ph.D.
January 8, 2014

Joseph E. Gaugler, PhD
Associate Professor
McKnight Presidential Fellow
School of Nursing
University of Minnesota
5-140 Weaver Densford Hall
308 Harvard Street SE
Minneapolis, MN  55455

Dear Dr. Gaugler,

The Institute of Health Informatics would be happy to support your evaluation of the remote sensor technology system, "eNeighbor," for persons with dementia and their family caregivers that you are proposing in your R18 application to the Agency for Healthcare Research and Quality. We acknowledge that you will be working closely with Dr. Bonnie Westra, an associate professor in the School of Nursing, the School of Nursing informatics specialty coordinator and is on the leadership team of the Institute for Health Informatics. We acknowledge that you will be relying on several elements of the Clinical and Translation Sciences Institute: the Biostatistical Design and Analysis Center (Philippe Gaillard, PhD, will serve as the project biostatistician), the Biomedical Health Informatics core (you plan to utilize the REDcap web-based data collection and management system as well as the UMN Profiles service to promote your work), and the Delaware Clinical Research Unit to conduct follow-up interviews for study participants. We also can assist in referring you to other resources supportive of your evaluation of health monitoring technology for persons with dementia and their family caregivers.

We are excited to lend support to this project!

Sincerely,

Connie White Delaney, PhD, RN, FAAN, FACMI
School of Nursing Professor & Dean
Academic Health Center
Director, Biomedical Health Informatics (BMHI)
Associate Dir. CTSI-BMI
Acting Dir. of the Institute for Health Informatics (IHI)
16540 43rd Ave. No
Plymouth, MN 55446
May 8, 2013

Joseph E. Gaugler, Ph.D.
Associate Professor, McKnight Presidential Fellow
Editor-in-Chief, Journal of Applied Gerontology
School of Nursing, Center on Aging
University of Minnesota
6-153 Weaver-Densford Hall, 1331
308 Harvard Street S.E.
Minneapolis, MN 55455

Dear Dr. Gaugler,

I enthusiastically support your proposed project to develop, test, and disseminate health monitoring technology for families who care for loved ones with Alzheimer's disease or a related dementia. Your proposal that you are planning to submit to the Agency for Healthcare Research and Quality sounds exciting and I am thrilled to be a part of this potentially groundbreaking project. As someone who provides personal care to my husband with dementia, I am certain that the home health monitoring technology you plan to evaluate will be of great use to families and professionals alike.

By submitting this letter of support, I agree to sit on the project's Community Advisory Board and provide oversight to all aspects of your project. I look forward to meeting with you and the rest of the board every 4 months to direct study and project questions, oversee study progress, interpret results with you collaboratively, and facilitate dissemination to traditional and non-traditional audiences. Currently, I work at the University of Minnesota, as a Coordinator of Multicultural Programs and in the community as meditator. I am also the caregiver for my husband who was diagnose four years ago with dementia. For these reasons, I have a strong interest in your project.

I am enthusiastic about being a member of the Community Advisory Board, and I agree to meet with you every 4 months during the 5 years of this project. I will assist you helping to determine how home health monitoring technology can help professionals and family caregivers such as myself.

Sincerely,

Venoreen Browne-Boatswain

Venoreen Browne-Boatswain
January 7, 2014

Joseph E. Gaugler, Ph.D.
Associate Professor, McKnight Presidential Fellow
Editor-in-Chief, Journal of Applied Gerontology
School of Nursing, Center on Aging
University of Minnesota
6-153 Weaver-Densford Hall, 1331
308 Harvard Street S.E.
Minneapolis, MN 55455

Dear Dr. Gaugler/Joe,

I enthusiastically support your proposed project to develop, test, and disseminate health monitoring technology for families who care for loved ones with Alzheimer’s disease or a related dementia. Your proposal that you are planning to submit to the Agency for Healthcare Research and Quality sounds exciting and I am thrilled to be a part of this potentially groundbreaking project. As someone who provides professional support to people with dementia, I am certain that the home health monitoring technology you plan to evaluate will be of great use to families and professionals alike.

By submitting this letter of support, I agree to sit on the project’s Community Advisory Board and provide oversight to all aspects of your project. I look forward to meeting with you and the rest of the board every 4 months to direct study and project questions, oversee study progress, interpret results with you collaboratively, and facilitate dissemination to traditional and non-traditional audiences.

I am the Director of Community Partners, A Living at Home/Block Nurse Program, located in the Northeastern MN Community of Two Harbors. Our program provides services to help older adults live at home. Our services include Caregiver Support for those who care for their loved ones with Dementia. We provide counseling, support groups, service coordination and respite care. Your proposed project is an innovative idea for meeting the needs of the people we serve. For this reason, I have a strong interest in your project.

I am enthusiastic about being a member of the Community Advisory Board, and I agree to meet with you every 4 months during the 5 years of this project. I will assist you helping to determine how home health monitoring technology can help professionals and family caregivers such as myself.

Sincerely,

Kirsten Cruikshank, MSW, LGSW
Community Partners, Two Harbors Living at Home/Block Nurse Program
P.O. Box 327
Two Harbors, MN 55616
commpart@frontiernet.net
218-834-8024
January 13, 2013

Dear Dr. Gaugler/Joe,

I enthusiastically support your proposed project to develop, test, and disseminate health monitoring technology for families who care for loved ones with Alzheimer's disease or a related dementia. Your proposal that you are planning to submit to the Agency for Healthcare Research and Quality sounds exciting and I am thrilled to be a part of this potentially groundbreaking project. As someone who provides professional and/or personal care to someone with dementia, I am certain that the home health monitoring technology you plan to evaluate will be of great use to families and professionals alike.

By submitting this letter of support, I agree to sit on the project's Community Advisory Board and provide oversight to all aspects of your project. I look forward to meeting with you and the rest of the board every 4 months to direct study and project questions, oversee study progress, interpret results with you collaboratively, and facilitate dissemination to traditional and non-traditional audiences. For almost a decade, I have been providing Adult Day Health Services (formerly SarahCare) and In-Home Care and most recently was awarded the Innovation in Healthcare award at the 2012 Achieve! Awards by NAWBO-MN. In addition, I am an agent for GrandCare Home Monitoring systems that I will be using in my Person-Centered Residential Medical Homes as well as sell them to families who are in need of home monitoring. For these reasons, I have a strong interest in your project.

I am enthusiastic about being a member of the Community Advisory Board, and I agree to meet with you every 4 months during the 5 years of this project. I will assist you helping to determine how home health monitoring technology can help professionals and family caregivers such as myself.

Warmest regards,

Deborah K. Delaney
Founder/CEO
Flagship Franchises of MN, Inc.
Touching Lives Adult Day Services
Touching Lives Communities
4833 W. 123rd Street
Savage, MN 55378
January 9, 2014

Dear Joe,

I am in strong support of your proposal, "Evaluating Home Health Monitoring Technology for Dementia Caregivers" to the Agency for Healthcare Research & Quality. As an experienced geriatric nurse care manager, with a 10 year care management practice that centers on serving older persons with dementia and their families, I am excited about your efforts to identify those dementia caregiver intervention models that are most beneficial for family caregivers of persons with Alzheimer's disease or a related dementia. Most importantly, I think creating an online/mobile device care planning tool to provide day-to-day support for family caregivers will greatly advance our state-of-the-art. It is a timely and proactive proposal that is particularly relevant for our technology based and busy world.

By submitting this letter of support, I agree to sit on the project's Community Advisory Board. As you know based on our past collaborations (including my speaking at your annual Caring for a Person with Memory Loss) and my own work, such as speaking for the Alzheimer’s Association’s Annual Meeting of the Minds conference, serving as a facilitator of caregiver support groups and, the hundreds of family consultations I have done, I am committed to serving and helping family caregivers of persons with Alzheimer's disease or a related dementia.

I am excited to serve as a member of your Community Advisory Board, which will meet once every 4 months during the 5 years of this project. I will assist you in ascertaining how your person-centered research and translational activities can be refined to help families and persons with dementia. I greatly appreciate this opportunity!

Sincerely,

Kathleen Dempsey, RN, C, BSN
January 10th, 2014

Dear Dr. Gaugler,

This letter is to support your proposal submission to the Agency for Healthcare Research and Quality to evaluate home health monitoring technology for persons with dementia and their family caregivers. I am excited to be a part of this project to assist you and your team to deliver and evaluate this innovative technology for family caregivers. Given our work with families, we believe in the use of effective and appropriate technology to help families caring for a loved one with memory loss.

By submitting this letter of support, I agree to sit on the project's Community Advisory Board. As you know based on my own work as a social worker with seniors at Park Nicollet Clinic for over 15 years, I have a strong interest in providing assistance and support to persons with Alzheimer's disease or a related dementia.

I look forward to being a part of the Community Advisory Board, and I agree to meet with you every four months during the five years of this project. I will help you determine how to optimize the delivery of the health monitoring technology and how you can optimally evaluate this technology to best meet the needs of persons with dementia and their family caregivers.

Sincerely,

Karen Gallagher, LISW
Geriatric Social Worker
Park Nicollet Clinic
January 7, 2014

Joseph E. Gaugler, Ph.D.
Associate Professor, McKnight Presidential Fellow
Center on Aging, School of Nursing
Coordinator of Research Initiatives, Center for Gerontological Nursing
University of Minnesota
6-153 Weaver-Densford Hall, 1331
308 Harvard Street S.E.
Minneapolis, MN 55455

Dear Dr. Gaugler/Joe,

I enthusiastically support your proposed project to develop, test, and disseminate health monitoring technology for families who care for loved ones with Alzheimer’s disease or a related dementia. Your proposal that you are planning to submit to the Agency for Healthcare Research and Quality sounds exciting and I am thrilled to be a part of this potentially groundbreaking project. As someone who provides professional and/or personal care to someone with dementia, I am certain that the home health monitoring technology you plan to evaluate will be of great use to families and professionals alike.

By submitting this letter of support, I agree to sit on the project’s Community Advisory Board and provide oversight to all aspects of your project. I look forward to meeting with you and the rest of the board every 4 months to direct study and project questions, oversee study progress, interpret results with you collaboratively, and facilitate dissemination to traditional and non-traditional audiences. I am a Licensed Clinical Social Worker with over 20 years of experience in working with individuals with dementia and their families in both residential and counseling settings. Additionally, my husband’s grandmothers passed away from Alzheimer’s disease and have first-hand experience with being a part of a primary care team to support both her and her husband in their home. For these reasons, I have a strong interest in your project.

I am enthusiastic about being a member of the Community Advisory Board, and I agree to meet with you every 4 months during the 5 years of this project. I will assist you helping to determine how home health monitoring technology can help professionals and family caregivers such as myself.

Sincerely,

Heidi Haley-Franklin, LICSW
Heidi Haley-Franklin, MSW, LICSW
Director of Clinical Services
Alzheimer’s Association Minnesota-North Dakota
7900 West 78th Street, Suite 100
Minneapolis, MN 55439
January 7, 2014

Joseph E. Gaugler, Ph.D.
Associate Professor, McKnight Presidential Fellow
Editor-in-Chief, Journal of Applied Gerontology
School of Nursing, Center on Aging
University of Minnesota
6-153 Weaver-Densford Hall, 1331
308 Harvard Street S.E. Minneapolis,
MN 55455

Dear Dr. Gaugler,

I enthusiastically support your proposed project to develop, test, and disseminate health monitoring technology for families who care for loved ones with Alzheimer’s disease or a related dementia. Your proposal that you are planning to submit to the Agency for Healthcare Research and Quality sounds exciting and I am thrilled to be a part of this potentially groundbreaking project. As someone who provides professional technology and/or personal care to someone with dementia, I am certain that the home health monitoring technology you plan to evaluate will be of great use to families and professionals alike.

By submitting this letter of support, I agree to sit on the project’s Community Advisory Board and provide oversight to all aspects of your project. I am looking forward to meeting with you and the rest of the board every 4 months to direct study and project questions, oversee study progress, interpret results with you collaboratively, and facilitate dissemination to traditional and non-traditional audiences.

My mother passed almost two years ago. You know how it’s said that hindsight is 20/20? I can think of a dozen things I could have done better. A simple camera could have told me much earlier than her wonderful health aide did (when she arrived 2 hours after the incident) that my mother had had a serious fall and broken both of her shoulders and I could have gotten help to her right away. If I had better monitoring equipment – equipment I could trust to wake me, I might have been able to sleep at night, at least for an hour or two. It is important for people to find the right mix of technology and human touch, and the funds to provide both. For these reasons, I have a strong interest in your project.

I am enthusiastic about being a member of the Community Advisory Board, and I agree to meet with you every 4 months during the 5 years of this project. I will assist you helping to determine how home health monitoring technology can help professionals and family caregivers such as myself.

Sincerely,

Kate (Kathryn) Knapp
1324 Jordan Ave. S.
St. Louis Park, MN 55426

Personal Cell: 952-334-2933
kateknapp@gmail.com
1/7/14

Joseph E. Gaugler, Ph.D.
Associate Professor, McKnight Presidential Fellow
Editor-in-Chief, Journal of Applied Gerontology
School of Nursing, Center on Aging
University of Minnesota
6-153 Weaver-Densford Hall, 1331
308 Harvard Street S.E.
Minneapolis, MN 55455
Dear Dr. Gaugler/Joe,

I enthusiastically support your proposed project to develop, test, and disseminate heath monitoring technology for families who care for loved ones with Alzheimer’s disease or a related dementia. Your proposal that you are planning to submit to the Agency for Healthcare Research and Quality sounds exciting and I am thrilled to be a part of this potentially groundbreaking project. As someone who provides professional and/or personal care to someone with dementia, I am certain that the home health monitoring technology you plan to evaluate will be of great use to families and professionals alike.

By submitting this letter of support, I agree to sit on the project’s Community Advisory Board and provide oversight to all aspects of your project. I look forward to meeting with you and the rest of the board every 4 months to direct study and project questions, oversee study progress, interpret results with you collaboratively, and facilitate dissemination to traditional and non-traditional audiences. I am the Director of Housing and Home Care for four assisted living buildings two of which have secured memory care units. I have been with the company for nearly 10 years and have been touched by so many people that I have cared for. I am also active with Aging services of MN and have sat on their Housing Cabinet for the past 5 years. I am truly passionate about serving our greatest generation. For these reasons, I have a strong interest in your project.

I am enthusiastic about being a member of the Community Advisory Board, and I agree to meet with you every 4 months during the 5 years of this project. I will assist you helping to determine how home health monitoring technology can help professionals and family caregivers such as myself.

Sincerely,

[Signature]

Danielle Lesmeister, RN
Director of Housing and Home Care
Skyview/Suncrest/Pines III
1100 court Dr
Morris MN 56267
320-589-4582
dlesmeister@sfhs.org
Dear Dr. Gaugler,

I am in strong support of your proposal submission to the Agency for Healthcare Research and Quality to evaluate home health monitoring technology for persons with dementia and their family caregivers. As an experienced geriatric nurse practitioner that coordinates an interdisciplinary clinic serving older persons with dementia and their families, I am excited about your efforts to evaluate home health monitoring technology for family caregivers of persons with Alzheimer's disease or a related dementia. Most importantly, I think implementing and evaluating this technology will greatly advance our state-of-the-art of community-based dementia care.

By submitting this letter of support, I agree to sit on the project's Community Advisory Board. As you know, based on our past collaborations and my own work in clinic and teaching/learning settings, I am committed to serving and helping family caregivers of persons with Alzheimer's disease or a related dementia live as high a quality of life as possible. I am interested in supporting new and innovative ways to enhance these efforts, such as developing usable technology.

I am excited to serve as a member of your Community Advisory Board, which will meet once every 4 months during the 5 years of this project. I will help you determine how to optimize the delivery of the health monitoring technology and how you can optimally evaluate this technology to best meet the needs of persons with dementia and their family caregivers. I am excited to continue our ongoing collaboration.

Sincerely,

Siobhan McMahon, PhD, MPH, GNP-BC
Assistant Professor
January 6, 2014

Joseph E. Gaugler,
Ph.D. Associate Professor,
McKnight Presidential Fellow Editor-in-Chief, Journal of Applied Gerontology School of Nursing,
Center on Aging University of Minnesota
6-153 Weaver-Densford Hall,
1331 308 Harvard Street S.E. Minneapolis, MN 55455

Dear Dr. Joe Gaugler:

I enthusiastically support your proposed project to develop, test, and disseminate health monitoring technology for families who care for loved ones with Alzheimer's disease or a related dementia. Your proposal that you are planning to submit to the Agency for Healthcare Research and Quality sounds exciting and I am thrilled to be a part of this potentially groundbreaking project. As someone who provides professional and/or personal care to someone with dementia, I am certain that the home health monitoring technology you plan to evaluate will be of great use to families and professionals alike. By submitting this letter of support, I agree to sit on the project's Community Advisory Board and provide oversight to all aspects of your project. I look forward to meeting with you and the rest of the board every 4 months to direct study and project questions, oversee study progress, interpret results with you collaboratively, and facilitate dissemination to traditional and non-traditional audiences.

I am a retired IBM executive who has been involved in startup companies since I left IBM. I have served on several boards of companies that have a direct interest in improving aging. My wife was diagnosed with Mild Cognitive Impairment nearly 4 years ago and we have participated in Mayo Clinic training and volunteer to address HABIT class offerings by Mayo Clinic.

I serve on the board of Mill City Commons which is a village approach to community building with the goal of assisting in aging in place for older people living in an urban environment. For these reasons, I have a strong interest in your project.

I am an active participant on the Board of Trustees at ECUMEN Inc which is a large owner/operator of elder homes from independent living to memory care. I am on an advisory board which supports new startups with the hopes of assisting in the development of technology that will aid aging.

I am enthusiastic about being a member of the Community Advisory Board, and I agree to meet with you every 4 months during the 5 years of this project. I will assist you helping to determine how home health monitoring technology can help professionals and family caregivers such as myself.

Sincerely,

A Richard Olson

A. Richard Olson
45 University Ave SE Unit 610
Minneapolis, MN 55414-1196
Minneapolis, MN 55455
(612) 331-9798
aromolson@gmail.com
January 17, 2014

Joseph E. Gaugler, Ph.D.
Associate Professor, McKnight Presidential Fellow
School of Nursing, Center on Aging
University of Minnesota
6-153 Weaver-Densford Hall, 1331F
308 Harvard Street SE
Minneapolis, MN 55455

RE: Letter of support for submission to Agency for Healthcare Research and Quality

Dear Dr. Gaugler:

This letter is to support your proposal submission to the Agency for Healthcare Research and Quality to evaluate home health monitoring technology for persons with dementia and their family caregivers. I enthusiastically support your efforts to evaluate how this emerging technology can be put to ideal use to offer additional support to family caregivers of persons with Alzheimer’s disease or a related dementia.

By submitting this letter of support, I agree to sit on the project’s Community Advisory Board. As you know, based on our past collaborations – including my speaking at your annual Caring for a Person with Memory Loss – and my own work as a health services researcher in geriatrics, as a member and current President of the American Geriatrics Society, and as a geriatrics clinician for the past 20 years, I am committed to serving and helping family caregivers of persons with Alzheimer’s disease or a related dementia.

I value serving as a member of your Community Advisory Board, which will meet once every 4 months during the five years of this project. In particular, I will help you determine how to optimize the delivery of the health monitoring technology and how you can optimally evaluate this technology to best meet the needs of persons with dementia and their family caregivers. I am excited to continue our ongoing collaboration.

Sincerely,

James Pacala, MD, MS
Distinguished Teaching Professor and Acting Head
Department of Family Medicine and Community Health
University of Minnesota Medical School
January 8, 2014

Dear Dr. Gaugler,

I am excited to submit this letter of support for your proposal to the Agency for Healthcare Research and Quality to evaluate home health monitoring technology for persons with dementia and their family caregivers. I will gladly provide an occupational therapy perspective to the development and refinement of your online care planning tool for family caregivers of persons with dementia. Providing innovative technology to family caregivers is an exciting idea, and aligns well with quality chronic disease care objectives.

By submitting this letter of support, I agree to sit on the project's Community Advisory Board. As you know based on my own work including authorship of the Occupational Therapy Practice Guidelines for Adults with Alzheimer's disease and Related Disorders and my service on the Medical and Scientific Advisory Board of the Alzheimer's Association, I have a strong interest in providing assistance and support to persons with Alzheimer's disease or a related dementia. I look forward to serve as a member of your Community Advisory Board, which will meet once every 4 months during the 5 years of this project. I will assist you in ascertaining how your person-centered research and translational activities can be refined to help families and persons with dementia. Thank you for the invitation!

Sincerely,

Patricia Schaber, PhD, OTR/L
January 15, 2014

Joseph E. Gaugler, Ph.D.
Associate Professor, McKnight Presidential Fellow
Editor-in-Chief, Journal of Applied Gerontology
School of Nursing, Center on Aging
University of Minnesota
6-153 Weaver-Densford Hall, 1331
308 Harvard Street S.E.
Minneapolis, MN 55455

I enthusiastically support your proposed project to develop, test, and disseminate an online and mobile device care planning tool for families who care for loved ones with Alzheimer's disease or a related dementia. Your proposal, "Care to Plan: An online, Mobile, Person-Centered Care Planning Tool" that you are planning to submit to the Patient Centered Outcome Research Institute (PCORI) sounds exciting and I am thrilled to be a part of this potentially groundbreaking project. As someone who provides professional and/or personal care to someone with dementia, I am certain that the Care to Pan will be of great use to families and professionals alike.

By submitting this letter of support, I agree to sit on the project's Community Advisory Board and provide oversight to all aspects of your project. I look forward to meeting with you and the rest of the board every 4 months to direct study and project questions, oversee study progress, interpret results with you collaboratively, and facilitate dissemination to traditional and non-traditional audiences.

As a psychologist, I understand the complexities of managing a disease such as Alzheimer's, for the person affected as well as for the family that cares for this person. I am also a caregiver for a family member who has early onset Alzheimer's disease. Through this experience, I have learned how challenging it is to coordinate the many aspects of care, as well as manage the increasing needs, especially for a young person with the disease. For these reasons, I have a strong interest in your project.

I am enthusiastic about being a member of the Community Advisory Board, and I agree to meet with you every 4 months during the 3 years of this project. I will assist you in helping determine how your online care planning tool can help professionals and family caregivers such as myself.

Sincerely,

Kathleen Schaefers, Ph.D.
651-260-8562
corelife@earthlink.net
January 10, 2014

Joseph E. Gaugler, Ph.D.
Associate Professor, McKnight Presidential Fellow
Editor-in-Chief, Journal of Applied Gerontology
School of Nursing, Center on Aging
University of Minnesota
6-153 Weaver-Densford Hall, 1331
308 Harvard Street S.E.
Minneapolis, MN 55455

Dear Dr. Gaugler,

I enthusiastically support your proposed project to develop, test, and disseminate health monitoring technology for families who care for loved ones with Alzheimer's disease or a related dementia. Your proposal that you are planning to submit to the Agency for Healthcare Research and Quality sounds exciting and I am thrilled to be a part of this potentially groundbreaking project. As someone who provided personal care to someone with dementia, I am certain that the home health monitoring technology you plan to evaluate will be of great use to families and professionals alike.

By submitting this letter of support, I agree to sit on the project's Community Advisory Board and provide oversight to all aspects of your project. I look forward to meeting with you and the rest of the board every 4 months to direct study and project questions, oversee study progress, interpret results with you collaboratively, and facilitate dissemination to traditional and non-traditional audiences.

In addition to my professional experience in Talent Management and Organization in the Human Resources field, I've worked with several non-profit organizations, including Parkinson's Association of the Rockies (Denver, CO). My father, who had Parkinson's Disease for over 16 years, also had dementia. He progressed in the disease, and ultimately spent the last year of his life at a memory care facility in Minneapolis as he continue to decline under hospice care.

Throughout the progression of my father's disease, we wished for more guidance and planning tools. Now I would like to share any learnings we had as a family in the hopes of assisting others, and for these reasons, I'm very interested in this great project you're embarking on, and am enthusiastic about being a member of the Community Advisory Board. I agree to meet with you every 4 months during the 5 years of this project. I will assist you helping to determine how home health monitoring technology can help professionals and family caregivers such as myself.
Sincerely,

Francis Scheve
1126 Preserve Circle
Golden, CO  80401
fmscheve@yahoo.com
January 15, 2014

Joseph E. Gaugler, Ph.D.
Associate Professor, McKnight Presidential Fellow
Editor-in-Chief, Journal of Applied Gerontology
School of Nursing, Center on Aging
University of Minnesota
6-153 Weaver-Densford Hall, 1331
308 Harvard Street S.E.
Minneapolis, MN 55455

Dear Dr. Gaugler:

I enthusiastically support your proposed project to develop, test, and disseminate a health monitoring intervention for caregivers of loved ones with dementia. Your proposal, A Proactive Health Monitoring Intervention for Dementia Caregivers: The eNeighor, that you are submitting to the Agency for Healthcare Quality & Research sounds exciting and I am thrilled to be a part of this potentially groundbreaking project. As someone who provides personal care to someone with dementia, I am certain that this proposal will be of great use to families and professionals alike.

By submitting this letter of support, I agree to sit on the project’s Community Advisory Board and provide oversight to all aspects of your project. I look forward to meeting with you and the rest of the board every 4 months to direct study and project questions, oversee study progress, interpret results with you collaboratively, and facilitate dissemination to traditional and non-traditional audiences.

I am a primary caregiver to my 82 year old mother who has moderate/advanced dementia/probable Alzheimer’s and who presently is in a memory care center in Massachusetts. As a long distance caregiver, your project is of particular interest to me. I have a graduate certificate in Aging Studies from the School of Public Health at the University of Minnesota and serve on the Caregiver Advisory Board to the Amherst H. Wilder Foundation’s Capacity to Care Initiative. For these reasons, I have a strong interest in your project.

I am enthusiastic about being a member of the Community Advisory Board, and I agree to meet with you every 4 months for the duration of this project. I will assist you helping to determine how your online care-planning tool can help professionals and family caregivers such as myself.

Sincerely,

[Signature]

Paul V. Snyder, MSW, MDiv
Manager, Minnesota Partnership for School Connectedness (MPSC)
Social Work Faculty, Leadership Education in Adolescent Health (LEAH) Fellowship Program
Adjunct Faculty, University of Minnesota School of Social Work
Konopka Institute for Best Practices in Adolescent Health
717 Delaware St SE – Rm 373
Minneapolis, MN 55414
phone: 612-799-7821
email: psnyder@umn.edu
January 17, 2014

Joseph E. Gaugler, PhD.
Associate Professor
School of Nursing, Center on Aging
University of Minnesota
6-153 Weaver-Densford Hall, 1331
308 Harvard Street S.E.
Minneapolis, MN 55455

Dear Dr. Gaugler/Joe,

This letter is to fully support your proposal, “Enhancing Adult Day Service Outcomes through the Implementation of Evidence-Based Interventions”. I am excited to serve as a consultant on this project. I am a firm believer in the benefits of the multi component intervention approaches to assist persons with dementia and their family caregivers, and I am happy to lend my assistance in helping you and your project implement the NYUCI in Minnesota adult day service programs. I see this project as extending our prior collaborations in integrating the NYUCI throughout the state of Minnesota. Your project will address an important need to extend the reach of the NYUCI and RADAD into adult day service programs, thus reaching even greater numbers of Minnesotans. Doing so will lead to more rigorous and beneficial dementia outcomes. For these reasons, your proposed project is highly likely to result in an effective, innovative approach to enhance adult day services in Minnesota and beyond.

This letter confirms that I will spend 48 hours in Years 1 through 5 at $100 per hour for a total of $4800 per year.

Sincerely,

Donna Walberg, MBA
Resource Sharing Plan

Community Advisory Board (CAB) members’ involvement in dissemination of project results will operate at multiple levels. First, CAB members will be invited to first-author or co-author any scientific or clinical peer-reviewed manuscripts, book chapters, posters/presentations, or similar reports. Second, we will encourage CAB members to identify less traditional methods of dissemination where they can promote any project-related result, contingent on approval from the CAB. For example, several of the CAB members host blogs or utilize social media. We hope to rely on this wider audience to disseminate some of the main findings and aspects of the health monitoring technology intervention to facilitate its use by dissemination to these various platforms. The project team and CAB are also ideally positioned to disseminate the results of the proposed demonstration project to various audiences; for example, Dr. Gaugler is a Fellow of the Gerontological Society of America and the American Psychological Association and holds or has held executive committee positions in these organizations. He also serves as editor and on the editorial boards of the leading journals in geriatrics and gerontology (Journal of Applied Gerontology; Journals of Gerontology: Psychological Sciences; Journals of Gerontology: Social Sciences; Psychology & Aging). Dr. Buckwalter is the Editor of Journal of Gerontological Research, is a Fellow of the American Academy of Nursing, and is an internationally-renowned geriatric nurse scientist. Dr. Bonnie Westra and Dr. Demiris also have leadership responsibilities, fellowship status, and editorial board memberships in nursing and health information technology organizations that will further strengthen the dissemination of the multiple peer-reviewed manuscripts and presentations to be produced from this study. Dr. Pacala, a member of the CAB, was president of the American Geriatrics Society. The Lutheran Home Association (TLHA) is a leading organization in implementing useful technology in long-term care in Minnesota, as evidenced by TLHA’s ongoing supports and grant awards from the Minnesota Department of Human Services. The project team’s and CAB members’ engagement in various organizations will maximize the impact of this multi-faceted dissemination effort.

To extend the project's dissemination impact and maintenance, results of the study will be available on a project web-page (located on the University of Minnesota's School of Nursing server but will also include acknowledgement of and cross-links to other participating institutions, organizations, blogs, and social media platforms represented by the CAB). The project web page will offer links to PDF and HTML files of a user-friendly final report, peer-reviewed manuscripts, and interactive webinar presentations from Dr. Gaugler or other members of the CAB who wish to demonstrate the utility of health monitoring technology for their professional colleagues or families that they have contact with. This web-based dissemination strategy will promote the local, state, and national implications of health monitoring technology for family caregivers of persons with ADRD. At the conclusion of this project, the School of Nursing Communications Office will draft a press release and media advisory summarizing the positive results, benefits, and utility of eNeighbor, and we will highlight the role of the CAB in these efforts and tailor such press releases so that individual members of the CAB can have their own roles in the eNeighbor evaluation process highlighted.

During the dissemination period (the final 6 months of the proposed 5-year project), a full training manual for programs and organizations interested in utilizing health monitoring technology will be made available on the project website. The training manual will include a description of the eNeighbor development and testing procedures, the assessment process and eNeighbor delivery, copies of the assessment protocol used to ascertain both implementation and feasibility for ADRD caregivers, and a step-by-step instruction guide for how to overcome barriers to use and to maximize utilities of health monitoring technology. The manual will also include the user-friendly final report which will summarize the potential benefits of offering health monitoring technology as an innovative, effective tool to manage disease severity in ADRD. The training manual will be made available on the project web site as a PDF file and will also be disseminated to the key stakeholder organizations listed above; the CAB members, who will have played an integral role in drafting and approving the final report and any other dissemination efforts will also distribute the results to their own constituencies (e.g., blog readers, hospital or community organization board of directors or other key staff; Minnesota state governmental officials such as the director of the Minnesota Board on Aging and Aging Disability and Resources Center). Contact information of the study team and CAB members will be available on the project web page to provide on-site or telephone consultation to facilitate health monitoring adoption activities. In this manner, the comprehensive resource sharing and dissemination plan will result in enhanced maintenance and use of eNeighbor well after the conclusion of the 5-year project period.

Public access to the research data generated from this study will be offered via de-identified data files maintained by the Principal Investigator, Dr. Gaugler. All personal identifiers of family caregivers of persons with Alzheimer’s disease or a related dementia (ADRD) participating in the study will be removed and replaced with random identification numbers prior to distributing WinZip data files. Dr. Gaugler plans to keep all data
from the proposed 5-year project on the secure School of Nursing shared server folder for 7 years following study completion. Potential external investigators will be asked to complete a data user agreement. Dr. Gaugler will oversee the distribution of public data during the course of the funding period and for an indefinite period thereafter.

To augment these resource sharing and dissemination activities, Dr. Gaugler will utilize his UMN Profiles page (http://profiles.ahc.umn.edu/display/231521). Dr. Gaugler will post any scientific manuscripts, poster presentations, webinars, or final reports of the proposed project to his UMN Profiles site. UMN Profiles sites are maintained by the Biomedical Informatics Core of the University of Minnesota Clinical and Translational Science Institute. UMN Profiles utilize social networking and other Web 2.0 features to further scientific dissemination and collaboration of investigators both within and beyond the University of Minnesota. Dr. Gaugler and the CAB will also consult with the Office of Discovery and Translation (ODAT; part of the University of Minnesota Clinical and Translational Science Institute; see http://www.ctsi.umn.edu/research/resources-for-basic-research/index.htm). ODAT assists researchers to identify effective approaches when translating evidence from scientific study into clinical practice. Dr. Gaugler and the CAB will consult with ODAT in Year 5 of the proposed project with the goal of utilizing various communication tools (e.g., blogs, social media, Wikipedia or other similar tools) to disseminate the findings related to the various Specific Aim procedures generated from this project.

In summary, the study team and the CAB members (who represent a range of stakeholders based on professional discipline and personal experiences with family caregiving) were selected to engage in the development and evaluation of health monitoring technology for families of relatives with ADRD as well as facilitate a multi-faceted dissemination effort. Dissemination will thus occur not only via traditional mechanisms (e.g., peer-reviewed publications or professional conferences) but also via informal networks of family caregivers, blogs, webinars and other presentations via our project web-page and a range of other strategies that our CAB members specialize in.