Pilot Research Grant Overview
The purpose of the UManage Center Pilot Research grant program is to provide funding for pilot research projects that address the self-management of sleep or fatigue using handheld or wearable sensors and/or other advanced technologies. Pilot projects support studies on the self-management of fatigue and sleep in persons of all age groups with chronic and acute disorders or multiple chronic conditions.

UManage Pilot Research grants enable faculty to generate data to support a subsequent NIH grant application. Submission of a NIH grant proposal is a requirement of a UManage Pilot Project grant award. Individuals awarded UManage Center grants will be recognized as UManage Center Research Fellows.

Grant applications that focus on any area of science related to the self-management of sleep and fatigue to improve human health are invited. This year we will fund at least one pilot grant focused on sleep, sleep management, sleep hygiene, sleep apnea or other area of sleep science. Two pilot awards will be made for 2019-20.

Funding Period
May 1, 2019 to April 30, 2020

Total Award Amount
The total award amount is $50,000 (Total direct cost). No indirect costs are allowed on pilot grant awards.

Letter of Intent (LOI)
Individuals who plan to submit a Pilot Project grant application are required to submit a Letter of Intent (LOI). The LOI (2 page limit) summary should include: 1) an abstract/summary of the proposed grant application that is responsive to the RFA (and outlines the introduction/purpose, objective(s), and proposed method(s)); 2) Name of proposed principal investigator (PI); and 3) Names of other co-investigators/key personnel and their college/institutional affiliation. The deadline for the LOI is midnight, August 1, 2018.

Those submitting a LOI will be notified by August 15, 2018 if they are invited to submit a full grant application. Letters of intent should be submitted to Dr. Annette Wysocki, Director of the Pilot Project Core (annettew@nursing.umass.edu) with a cc to Dr. Ian Cooke (icooke@umass.edu), Office of Research, College of Nursing, University of Massachusetts Amherst. Following notification to submit a full proposal pilot project PIs are required to work with the UManage Team to develop a full proposal at weekly/bi-weekly meetings.

Purpose
The purpose of the UManage Center is to develop the capacity of nurse scientists to build the science of symptom self-management with a multidisciplinary team of investigators using handheld and wearable devices/sensors/technologies to address the symptoms of fatigue and sleep disturbances. Chronic disease affects the quality of life of more than 90 million Americans spanning the lifespan from children, to adults, to older Americans. While the focus of this RFA is fatigue and sleep disturbance, it is well known that these symptoms occur in symptom clusters and that often individuals actually experience from 4-10 symptoms needing self-management and result from the complex interaction of biological, behavioral, cognitive, sociocultural, spiritual and environmental factors.

Applicants are encouraged to develop proposals that also address or include attention to health disparities and leverage the resources of other on and off-campus resources. For example, the resources found in other UMass Centers and Institutes, the Institute for Applied Life Sciences, Center for Personalized Health Monitoring, the UMass CCTS (a federally funded CTSA), Institute for Social Science Research, Center for Research on Families and partnering Departments, Schools and Colleges, such as the College of Engineering, College of Information and Computer Sciences, Department of Polymer Science, School of Public Health, Department of Brain and Psychological Sciences, and etc.
Eligibility Criteria
All University of Massachusetts Amherst College of Nursing tenure track, tenured, and/or clinical track nursing faculty holding a PhD and a nursing license are eligible to apply for a UManage Pilot Project Award as the principal investigator (PI). The PI led team must include one or more scientific investigators from another discipline such as from the College of Natural Sciences, College of Engineering, School of Public Health and Health Sciences, College of Information and Computer Sciences, College of Humanity and Fine Arts, College of Social and Behavioral Sciences, College of Education, and/or Isenberg School of Management at the University of Massachusetts Amherst.

UMass Medical Center School of Nursing faculty are eligible to submit an application but must partner with a College of Nursing faculty member from the UMass Amherst College of Nursing campus to form a joint team and must include at least one other multidisciplinary team member or members from among the other Schools and Colleges on the University of Massachusetts Amherst campus to form a multidisciplinary team. Likewise, UMass Amherst nursing faculty PIs can partner with individuals inside and outside the applicant organization, including other nursing faculty at UMass Medical Center, but this is not required. All grant funds will be administered by the University of Massachusetts Amherst College of Nursing and all PIs will be required to meet the requirements for faculty investigators at the University of Massachusetts Amherst. Senior nursing faculty are eligible for pilot awards if they are developing a new area of investigation focused on the self-management of sleep and fatigue.

Pilot Project Applications
UManage Pilot Project grant applications should be written so that they conform to those of a federally funded R21 grant application and a Letter of Intent (LOI) is required prior to submission of the application (see above). Faculty selected to prepare a full application are required to work with the UManage Team and a mentor(s) to prepare the full application at weekly/biweekly meetings. Specific aims are to be written just as they would be for an application to the National Institutes of Health (NIH). Applications should follow the requirements of a federally funded application using an abbreviated format: 1) Specific Aims Page using NIH format – one (1) page limit; 2) Research Plan – six (6) page limit; 3) References – no page limit 4) Biosketch(s) using NIH template – five (5) page limit/person; 5) Budget – one (1) page limit; 6) PHS Human Subject and Clinical Trials Information Form set/Animal Subject Section and Inclusion Enrollment Report, if applicable, please contact the Office of Research for the required forms. Research Plans are to include an Introduction/Background section; Statement of Significance; Statement on Innovation; and Research Approach/Design: Design, Methods/Instruments, Data Analysis and a Timeline. Applications should be submitted by midnight October 15, 2018 to Dr. Annette Wysocki, (annettew@nursing.umass.edu), Director of the Pilot Project Core, UManage Center with a cc to Dr. Ian Cooke (icooke@umass.edu), Office of Research, College of Nursing, University of Massachusetts Amherst.

All applicants are required to have a Human Factors consult with Dr. Jenna Marquard, Core Director of the Human Factors Core who is in the Department of Mechanical and Industrial Engineering in the College of Engineering. Dr. Marquard can be contacted by e-mail at marquard@engin.umass.edu or telephone at 413-545-0646.

P20 Pilot Project PIs, you are required to enter data relating to your project into the Common Data Repository for Nursing Science (https://cdrns.nih.gov/) via the Biomedical Research Informatics Computing System (BRICS). This is part of an effort to develop Common Data Elements (CDEs) in nursing science. Consequently, applications are required to use Common Data Elements (CDE) where applicable, along with any other measures chosen by the investigator(s) in the design of the study to facilitate broader and more effective use of data, data sharing, advance standardization, improve data quality, enable data integration, and enable comparison of data from multiple studies. Currently these measures are for 1) demographics, 2) symptoms and 3) self-management and include: pain, fatigue, sleep disturbance, cognitive, affective-disturbance, affective anxiety, affective well-being, self-regulation, self-efficacy, and global health. These are defined in the Patient-Reported Outcomes Measurement Information System (PROMIS) located at healthmeasures.net. Future measures are under development.

Restrictions
All applications are subject to review and final approval by the National Institute of Nursing Research, National Institutes of Health. Grant applicants who are awarded a pilot project grant are required to have an eRA commons ID and upload grants to the NIH for final approval after selection by the P20 Pilot
Research Award Scientific Review Committee. There are no indirect costs or RTF funds available to the pilot research PI for this award.

Exclusion Criteria
Any faculty member who received a previous CON UManage Center Pilot Research grant award in the previous year, is not eligible to apply as the principal investigator for the grant this year. And those who subsequently receive an NIH grant are also not eligible. However, previous awardees may be a part of a research team. UManage Center Pilot Research Awards are not intended to support currently funded programs of research.

Letter of Intent Submission Deadline
August 1, 2018 (midnight)

Full Application Submission Deadline
October 15, 2018 (midnight)

Mock Review
November 1, 2018

Revisions Deadline
December 3, 2018

CON Notification of Award for Pilot Research Project
December 17, 2018

NINR/NIH Application Deadline (for all documents)
March 15, 2019

Following CON Notification of Award (NOA) PI’s will be required to prepare the final grant application for submission to NINR/NIH for approval. Additional information is required on: 1) Facilities and Other Resources; 2) Equipment; 3) Protection of Human Subjects and enrollment tables; and 4) Resource/Data Sharing Plan – including a statement regarding Sharing of Model Organisms; and Genome Wide Association Studies. The final full grant application will be required to conform to submission using SF424 instructions and forms and be uploaded to NINR/NIH through the Office of Grants and Contracts Administration (OGCA). If the pilot study meets the definition of a clinical trial then a data safety and monitoring plan (DSMP) must be submitted with the grant application relative to the level of risk (see https://humansubjects.nih.gov/data_safety). All Pilot Project grant awards are subject to FINAL approval by the NINR/NIH.

Outline of Application Materials & More Information (all full applications must conform to the NIH guidelines for an R21 grant)

1. Application Face Sheet (SF424 R&R page) – use the Application Face Sheet provided.
2. Specific Aims Page – the Specific Aims page should include a concise statement that identifies the area of research; identify critical gaps; state the long-term goal and central hypothesis; identify the specific aim(s); and include a statement of the expected outcome that has a public health implication(s). One (1) page limit.
3. Research Strategy – should include the following: an Introduction/Background section; Statement of Significance; Statement on Innovation; details about the Research Approach/Design: Design, Methods/Instruments/tools, and plans for Data Analysis. Include a statement of the potential for future funding and identify the source of proposed funding. Six (6) page limit.
4. References – Provide a list of references cited in the application. No page limit
5. Biosketch(es) – Provide a biosketch for the Principal Investigator and any Co-Investigators and/or key personnel using the NIH biosketch format. Five (5) page limit per person using the NIH Biosketch Form.
6. Budget and Budget Justification – The budget page should clearly outline how the focus grant will be spent and include such things as consultant fees, work study and non-work study student(s), data analysis fees, software, supplies, transcription fees, small equipment (less than
$2,500), subject costs, lab analysis fees, poster/abstract expenses, and etc. The budget should follow the NIH form used for a grant application.

7. **Facilities and Other Resources** – Description of the facilities, laboratories, resources you will use to conduct your pilot study

8. **PHS Human Subject and Clinical Trials Information Form set and Enrollment Report Form**

9. **Format** – For the application use one (1) inch margins with a font size of 11 or larger, no more than 15 characters per linear inch, no more than 6 lines per vertical inch, using either Arial, Garamond, Georgia, Helvetica, Palatino Linotype, Times New Roman or Verdana.

10. **NIH Defined Clinical Trials (CT)** – If your study is an NIH defined clinical trial then you will also need to prepare a Data Safety and Monitoring Plan (DSMP) that is appropriate to the level of risk associated with your study.

11. **Data Management Plan (DMP)** – You must also complete and submit a DMP for your pilot project along with an IRB approval letter prior to beginning your study.

**Selection Criteria**
The Scientific Review Committee will use the NIH criteria to evaluate the applications:

- Overall Impact
- Significance
- Investigator(s)
- Innovation
- Approach
- Environment

**Notification to Candidates**
Candidates will be notified by email upon receipt of their applications by the NINR/NIH. Final notification to award recipients will be emailed on or after March/May 2019 or upon notification of acceptance by NINR/NIH.

**External Advisory Panel**
Pilot project PI’s are required to prepare a slide presentation and other required materials for the annual review by the External Advisory Panel that typically occurs in March or April. Pilot project PI’s are expected to attend the External Advisory Panel meeting.

**Reporting Requirements see Quick Start Guide**
The awardees are required to submit a final report by March 1, 2020 to Dr. Cynthia Jacelon, Principal Investigator with use of funds and results of research to date for the annual Research Program Progress Report. The report will include an actual reconciled budget, describing how the funds were spent, and a one-page summary of the findings.

**NIH proposal Submission**
It is anticipated that the PI will submit a research grant proposal to NIH within 6 months of the conclusion of the pilot research project.

**Presentation**
Each recipient is also required to present a research seminar during the Fall or Spring semester of 2019-2020 about their proposed research with a subsequent presentation upon completion the following year. Thus, in the year the grant is awarded there will be a “research in progress” for the Fall and/or Spring of 2019-20 with another presentation to “report results of the completed research” seminar in the Fall or Spring of 2020-21. Each grant recipient should provide a title for their presentation to the Office of Research at least two weeks prior to their actual presentation.

Each recipient of a UManage Center grant is also expected to present at a national or international meeting on the results of their pilot project.

**Publication(s)**
The PI and their research team who have received a UManage Center Pilot Project grant award is expected to submit at least one manuscript for publication to a peer reviewed journal.

**Acknowledgement of Funding in All Presentations/Publications**
“Each publication, press release, or other document about research supported by an NIH award must include an acknowledgement of NIH award support and a disclaimer such as “Research reported in this publication was supported by the National Institute of Nursing Research of the National Institutes of Health under Award Number P20NR016599. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.” Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.”
College of Nursing
UManage Center Research Pilot Grant

Application Face Sheet

Date:____________________________________________________________________
Principal Investigator:_______________________________________________________
Faculty Rank:________________________________________________________________
Campus Address:____________________________________________________________
Telephone Number:_______________________________  E-mail: _____________________
Co-Investigator(s) and Department/College/School:________________________________

Title of UManage Center Research Grant:

Any use of:
Human subjects: ___Yes   ____No
Animal subjects: ___Yes    ____No
Biohazardous materials: ___Yes ___No
Clinical Trail: ____Yes ____No

Budget Requested:__________________________________________

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Recommendation: Funded __________________________ Not Funded____________________
Funding____________________________________ Date__________________________
Final Report Received______________________________ Date________________________
Reviewed_______________________________________ Date__________________________
Presentation Title ___________________________  Date________________________________
NIH Application Type ________________________ Date Submitted _______________________
NIH Application Title ____________________________
