Grant Number: 1R21NR012513-01A1

Principal Investigator(s):
Ann S Williams, PHD

Project Title: Nonvisual Foot Examination for People with Diabetes and Visual Impairment

Derrek M. Humphrey
Assistant Director
Case Western Reserve University
10900 Euclid Avenue
Cleveland, OH 441067015

Award e-mailed to: resadm@case.edu

Budget Period: 07/15/2011 – 06/30/2012
Project Period: 07/15/2011 – 06/30/2013

Dear Business Official:

The National Institutes of Health hereby awards a grant in the amount of $235,323 (see “Award Calculation” in Section I and “Terms and Conditions” in Section III) to CASE WESTERN RESERVE UNIVERSITY in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award including the “Terms and Conditions” is acknowledged by the grantee when funds are drawn down or otherwise obtained from the grant payment system.

Each publication, press release or other document that cites results from NIH grant-supported research must include an acknowledgment of NIH grant support and disclaimer such as “The project described was supported by Award Number R21NR012513 from the National Institute Of Nursing Research. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institute Of Nursing Research or the National Institutes of Health.”

Award recipients are required to comply with the NIH Public Access Policy. This includes submission to PubMed Central (PMC), upon acceptance for publication, an electronic version of a final peer-reviewed, manuscript resulting from research supported in whole or in part, with direct costs from National Institutes of Health. The author’s final peer-reviewed manuscript is defined as the final version accepted for journal publication, and includes all modifications from the publishing peer review process. For additional information, please visit http://publicaccess.nih.gov/

Award recipients must promote objectivity in research by establishing standards to ensure that the design, conduct and reporting of research funded under NIH-funded awards are not biased by a conflicting financial interest of an investigator. Investigator is defined as the Principal Investigator and any other person who is responsible for the design, conduct, or reporting of NIH-funded research or proposed research, including the Investigator’s spouse and dependent children. Awardees must have a written administrative process to identify and manage financial conflict of interest and must inform Investigators of the conflict of interest policy and of the Investigators' responsibilities. Prior to expenditure of these awarded funds, the Awardee must report to the NIH Awarding Component the existence of a conflicting interest and within 60 days of any new conflicting interests identified after the initial report. Awardees must comply with these and all other aspects of 42 CFR Part 50, Subpart F. These requirements also apply to subgrantees, contractors, or collaborators engaged by the Awardee under this award. The NIH website http://grants.nih.gov/grants/policy/coi/index.htm provides additional information.
If you have any questions about this award, please contact the individual(s) referenced in Section IV.

Sincerely yours,

Kelli Oster
Grants Management Officer
NATIONAL INSTITUTE OF NURSING RESEARCH

Additional information follows
SECTION I -- AWARD DATA -- 1R21NR012513-01A1

Award Calculation (U.S. Dollars)

Federal Direct Costs $166,031
Federal F&A Costs $69,292
Approved Budget $235,323
Federal Share $235,323
TOTAL FEDERAL AWARD AMOUNT $235,323

AMOUNT OF THIS ACTION (FEDERAL SHARE) $235,323

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Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project.

Fiscal Information:
CFDA Number: 93.361
EIN: JIN
Document Number: RNR012513A
Fiscal Year: 2011

IC CAN 2011 2012
NR 8472497 $235,323 $181,487

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project.

NIH Administrative Data:
PCC: CMEKJ/OC 414A/Processed: OSTERK 07/07/2011

SECTION II -- PAYMENT/HOTLINE INFORMATION -- 1R21NR012513-01A1

For payment and HHS Office of Inspector General Hotline Information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III -- TERMS AND CONDITIONS -- 1R21NR012513-01A1

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 74 or 45 CFR Part 92 as applicable.
d. The NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. This award notice, including THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at 'http://grants.nih.gov/grants/policy/awardconditions.htm' for certain references cited above.)

This institution is a signatory to the Federal Demonstration Partnership (FDP) Phase V Agreement which requires active institutional participation in new or ongoing FDP demonstrations and pilots.

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.
This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to receive a Dun & Bradstreet Universal Numbering System (DUNS) number and maintain an active registration in the Central Contractor Registration. Should a consortium/subaward be issued under this award, a DUNS requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award may be subject to the Transparency Act subaward and executive compensation reporting requirements of 2 CFR Part 170. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

This award provides support for one or more clinical trials. By law (Title VIII, Section 801 of Public Law 110-85), the “responsible party” must register “applicable clinical trials” on the ClinicalTrials.gov Protocol Registration System Information Website. NIH encourages registration of all trials whether required under the law or not. For more information, see http://grants.nih.gov/ClinicalTrials_fdaaa/

Treatment of Program Income:
Additional Costs

SECTION IV – NR Special Terms and Conditions – 1R21NR012513-01A1

INFORMATION: MODULAR GRANT AWARD
This is a modular grant award without direct cost categorical breakdown in accordance with the guidelines published in the NIH Grants Policy Statement (revised October 2010) (see http://grants.nih.gov/grants/policy/nihgps_2010/index.htm). Recipients are required to allocate and account for costs related to this award by category within their institutional accounting system in accordance with applicable cost principles.

INFORMATION: BUDGET PERIOD
Although the budget period start date for this award is 07/15/2011, this award includes funds for 12 months of support. Subsequent budget periods will begin on July 1, and will be for a 12 month duration. Allowable preaward costs may be charged to this award in accordance with the conditions outlined in the NIH Grants Policy Statement (revised October 2010) and with institutional requirements for prior approval.

INFORMATION: KEY PERSONNEL
In addition to the PI, any absence, replacement, or substantial reduction in effort of the following individual(s) below, requires the written prior approval of the National Institutes of Nursing Research.
Dr. Bryan Caldwell, Co-Investigator (Ohio College of Podiatric Medicine)

INFORMATION: CONSORTIUM/CONTRACTUAL COSTS
This award includes funds for consortium activity with Ohio College of Podiatric Medicine. Each consortium is to be established and administered in accordance with the NIH Grants Policy Statement dated October 2010. No foreign performance site may be added to this project without the written prior approval of the National Institute of Nursing Research.

INFORMATION: NINR ADJUSTMENTS FOR SALARY BASED AWARDS:
Salary funds provided on NINR research grants will be adjusted if investigators receive career-type salary based awards. In the event that such an award is made for an investigator receiving salary support from an NINR grant, the National Institute of Nursing Research must be informed in writing within 30 days from the start date of the award so that any required adjustment can be made.

INFORMATION: HUMAN SUBJECTS EDUCATION CERTIFICATION
This award reflects the National Institute of Nursing Research acceptance of the certification that all key personnel as defined in the February 29, 2008 NIH Guide announcement (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-054.html) have completed education on the protection of human subjects, in accordance with NIH policy requirements. Any key personnel, as defined in that announcement, who are not included in the JIT letter dated 4/28/2011 must satisfy this requirement prior to participating in the project. Failure to comply can result in suspension and/or termination of this award or withholding of support of the continuation award.

**STAFF CONTACTS**

The Grants Management Specialist is responsible for the negotiation, award and administration of this project and for interpretation of Grants Administration policies and provisions. The Program Official is responsible for the scientific, programmatic and technical aspects of this project. These individuals work together in overall project administration. Prior approval requests (signed by an Authorized Organizational Representative) should be submitted in writing to the Grants Management Specialist. Requests may be made via e-mail.

**Grants Management Specialist:** Judy Sint  
**Email:** sindj@mail.nih.gov  
**Phone:** 301-496-7240

**Program Official:** Joan Wasserman  
**Email:** wassermanje@mail.nih.gov  
**Phone:** 301-594-5071  
**Fax:** 301-480-6260

**SPREADSHEET SUMMARY**

**GRANT NUMBER:** 1R21NR012513-01A1

**INSTITUTION:** CASE WESTERN RESERVE UNIVERSITY

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**Subtotal Direct Costs (excludes consortium F&A)**
- Year 1: 150,000
- Year 2: 125,000

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**Senior/Key Personnel:**
- Ann Williams Ph.D. (Case Western Reserve University) - PD/PI
- Shirley Moore Ph.D (Case Western Reserve University) - Co-Investigator
- David Aron M.D. (Case Western Reserve University) - Co-Investigator
- Nahida Gordon Ph.D (Case Western Reserve University) - Co-Investigator
- Bryan Caldwell (Ohio College of Podiatric Medicine) - Co-Investigator
- Jill Carroll Ph.D (Ohio College of Podiatric Medicine) - Co-Investigator

**Appendix:**
Appendix2-universaldesignforlearning, Appendix3-initialscreening, Appendix4-enrollment, Appendix5-instructionsformultisafe, Appendix6-pediatryviamatom, Appendix7-focusgroupguide, Appendix1-universaldesign
APPLICATION FOR FEDERAL ASSISTANCE
SF 424 (R&R)

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

2. DATE SUBMITTED

3. DATE RECEIVED BY STATE

4. a. Federal Identifier
   - RRG12533

   b. Agency Routing Identifier

5. APPLICANT INFORMATION
   - * Organizational DUNS: 077758407
   - Legal Name: Case Western Reserve University
   - Department: Nursing
   - Division: Nursing
   - *Street1: 10900 Euclid Avenue
   - *City: Cleveland
   - *State: OH: Ohio
   - *Country: USA: UNITED STATES
   - * ZIP / Postal Code: 44106-7915
   - Person to be contacted on matters involving this application
   - Prefix:
   - * First Name: Deck
   - * Last Name: Humphrey
   - Suffix: N.
   - * Phone Number: 216.368.0510
   - Fax Number: 216.368.4679
   - Email: case44@case.edu

6. * EMPLOYER IDENTIFICATION (EIN) or (TIN): EIN

7. *TYPE OF APPLICANT:
   - 0: Private Institution of Higher Education
   - Other (Specify):
   - Small Business Organization Type
   - Women Owned
   - Socially and Economically Disadvantaged

8. *TYPE OF APPLICATION:
   - New
   - * Resubmission
   - If Revision, mark appropriate box(es).
   - A. Increase Award
   - B. Decrease Award
   - C. Increase Duration
   - D. Decrease Duration
   - E. Other (specify):
   - □ Renewal
   - □ Continuation
   - □ Revision
   - □ Is this application being submitted to other agencies? Yes
   - No
   - What other Agencies?

9. * NAME OF FEDERAL AGENCY:
   - National Institutes of Health

10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER:

11. * DESCRIPTIVE TITLE OF APPLICANT'S PROJECT:
    - Noninvasive Food Examination for People with Diabetes and Visual Impairment

12. PROPOSED PROJECT:
    - * Start Date: 07/01/2011
    - * Ending Date: 06/30/2013
    - 08-011

13. CONGRESSIONAL DISTRICT OF APPLICANT

14. PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR CONTACT INFORMATION
    - Prefix:
    - * First Name: Ant
    - * Last Name: Williams
    - Position/Title: Research Associate
    - * Organization Name: Case Western Reserve University
    - Department: Nursing
    - Division: Nursing
    - *Street1: 10900 Euclid Avenue
    - *City: Cleveland
    - *State: OH: Ohio
    - *Country: USA: UNITED STATES
    - * ZIP / Postal Code: 44106-7915
    - * Phone Number: 216.368.1704
    - Fax Number: 216.368.5307
    - * Email: awu136@case.edu

Tracking Number: GRANT10740010
Funding Opportunity Number: PA-10-069. Received Date: 2010-11-12T10:52:53-0600
## SF 424 (R&R) APPLICATION FOR FEDERAL ASSISTANCE

### 15. ESTIMATED PROJECT FUNDING

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<td>d. Estimated Program Income</td>
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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

### 17. Certification

- 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

* 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.

### 18. SFLLL or other Explanatory Documentation

### 19. Authorized Representative

- Prefix: 
- * First Name: Derek
- Middle Name: 
- Last Name: Humphrey
- Suffix: 
- * Position/Title: Assistant Director
- * Organization: Case Western Reserve University
- Department: Office of Sponsored Projects
- Division: 
- * Street 1: 10900 Euclid Avenue
- Street 2: 
- City: Cleveland
- County / Parish: 
- * State: OH, Ohio
- Province: 
- * Country: USA: UNITED STATES
- * ZIP / Postal Code: 44106-7015
- * Phone Number: 216.368.4510
- * Fax Number: 216.368.4679
- * Email: rossle@case.edu

* Signature of Authorized Representative

   - Derek Humphrey

* Date Signed

   - 11/12/2010

### 20. Pre-application
# 424 R&R and PHS-398 Specific Table Of Contents

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<td>Performance Sites</td>
<td>4</td>
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<td>Research &amp; Related Other Project Information</td>
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<td>PHS 398 Checklist</td>
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**Appendix**

*Number of Attachments in Appendix: 7*
**Project/Performance Site Location(s)**

**Project/Performance Site Primary Location**

- I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

  - **Organization Name:** Case Western Reserve University
  - **DUNS Number:** 0777584970000
  - **Street:** 10900 Euclid Avenue
  - **City:** Cleveland
  - **State:** OH: Ohio
  - **Country:** USA: UNITED STATES
  - **ZIP / Postal Code:** 44106-4904

**Project/Performance Site Location 1**

- I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

  - **Organization Name:**
  - **DUNS Number:**
  - **Street:**
  - **City:**
  - **State:**
  - **Country:** USA: UNITED STATES
  - **ZIP / Postal Code:**

**Additional Location(s):**

*Performance Sites*  

*Page 4*
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: 00004428

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.a. * Does this project have an actual or potential impact on the environment?  ☑ Yes  ☐ No
   4.b. If yes, please explain: _______________________________________________________
   4.c. 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?  ☚ Yes  ☐ No
   4.d. If yes, please explain: _______________________________________________________

5. * Is the research performance site designated, or eligible to be designated, as a historic place?  ☑ Yes  ☐ No
   5.a. If yes, please explain: _______________________________________________________

6. * Does this project involve activities outside of the United States or partnerships with international collaborators?  ☑ Yes  ☐ No
   6.a. If yes, identify countries: ___________________________________________________
   6.b. Optional Explanation: _______________________________________________________

7. * Project Summary/Abstract  1234-Abstract.pdf

8. * Project Narrative  1235-ProjectNarrative.pdf


10. Facilities & Other Resources  1237-Resources.pdf

11. Equipment

12. Other Attachments  View Attachment

Other Information

Tracking Number:GRANT107-0410

Funding Opportunity Number:PA-10-089 Received Date:2010-11-12T10:52:53-0400
NONVISUAL FOOT EXAMINATION FOR PEOPLE WITH DIABETES AND VISUAL IMPAIRMENT

People with both diabetes and visual impairment have high risk for serious, disabling, and potentially deadly foot problems. Foot self-examination is usually taught as a visual procedure, making it inaccessible to persons with visual impairment. The recommendation for usual care from both the American Diabetes Association (ADA) and the International Diabetes Federation (IDF) is that visually impaired people seek sighted assistance for daily foot examination. However, a simple, novel, low-technology intervention, Multiple Senses and Foot Evaluation (Multi-SAFE) uses nonvisual senses (touch and smell) to make foot self-examination accessible to people with visual impairment. This mixed-methods pilot study will compare the efficacy, acceptability, and feasibility of Multi-SAFE with usual care. The study aims are to: (1) compare frequency of foot examination between persons receiving the Multi-SAFE intervention and those receiving usual care, (2) assess the initial efficacy of the Multi-SAFE intervention for detection of new foot problems at home, (3) evaluate the feasibility of the Multi-SAFE intervention compared to usual care in terms of instructional time and classroom resources for teaching the Multi-SAFE intervention, (4) estimate effect size for sample size determination for a future, larger clinical trial, and (5) assess acceptability of Multi-SAFE compared to usual care. The proposed research will enroll 60 persons with diabetes and visual impairment, and use a 2-group randomized clinical trial comparing the Multi-SAFE intervention with usual care. All participants will receive comprehensive diabetes self-management education adapted for persons with visual impairment, including instruction in foot care. The experimental group will receive instruction in the Multi-SAFE intervention. The comparison group will receive usual care instructions for foot examination, which is having a sighted person examine their feet. Participants will be followed for 6 months in a podiatry clinic, with comprehensive podiatry examinations at baseline, at 3 and 6 months, and additional podiatry examinations if a new foot problem is discovered at home. Focus groups will be conducted with each class group after 6 months in the study. Outcome variables include frequency of foot examination at home, the percent of new foot problems developing during the study that were discovered at home, and instructional time and classroom resources. In addition, focus groups held following 6 months in the study will provide information from users about the acceptability of the Multi-SAFE intervention. If evidence supports the efficacy of the Multi-SAFE intervention, the short-term impact could be empowerment of persons with visual impairment to perform regular foot self-examination, resulting in improved detection and treatment of foot problems and substantial decreases in incidence of foot ulcers and amputations. The potential downstream impact is reduced costs of care for diabetes complications on the population level. For every 1% reduction in diabetic foot complications, costs would be reduced by $137 million.
In this pilot study we will compare the effects of teaching two different methods of foot examination to people who have diabetes and visual impairment: Multi-SAFE, a method for nonvisual foot examination that uses the senses of touch and smell, and usual care, which is to have a sighted person look at the feet. We will compare how often people actually examine their feet using each method; whether each method helps people to discover foot problems in early stages, when the problems are easier to treat; and how people feel about each method of examining their feet.
RESOURCES and ENVIRONMENT

CASE WESTERN RESERVE UNIVERSITY is an independent, research-oriented university with strengths in healthcare, including medicine, nursing, and dentistry; in engineering; in the arts and sciences; and in law, management, and social work. There are 9 Schools/Colleges: Case School of Engineering; College of Arts and Sciences; School of Graduate Studies; School of Dental Medicine; Frances Payne Bolton School of Nursing; School of Law; Mandel School of Applied Social Sciences; School of Medicine; and Weatherhead School of Management. The enriched environment of this large research university will allow the Principal Investigator (PI) and other members of the research team to access extensive learning and enrichment resources, including seminars and presentations on a wide range of relevant topics. In addition, informal networking opportunities exist both within the nursing and medical schools, and in other schools. Such a network offers many opportunities for enhancing knowledge, skills, and understanding of research design and methods.

The Libraries are divided into two major groups: The University Library and the Cleveland Health Sciences Library. Overall, these libraries house about 1.5 million items. The University Library features a variety of comfortable study spaces, up-to-date services, and collections that include over 1,290,000 monographs, 7,363 serial titles, U.S. Government publications, company annual reports, newspapers, CDs, technical reports, and more. In addition, approximately 200 databases are included on a powerful campus network that is accessible from both library workstations and office PCs throughout campus. CWRU is also a founding member of the OhioLINK consortia, allowing members of the community to access information electronically. Over 1,300 scholarly journals and other are available through this service, as well as other full-text articles and publications. The libraries give the PI and other members of the research team easy access to extensive journals, books, and other resources for information about current relevant research and methodologies.

Computer Services. Information Technology Services (ITS), is the central University organization responsible for the planning, installation, operation, support, maintenance, and continuous improvement of the campus network, general information technology services and resources and services in support of research and education. Among the services provided are: a centralized HelpDesk, a division of Instructional Technology and Academic Computing and a web-based Software Center for statistical software and the other software packages which can be accessed through the World Wide Web. In addition, ITS is responsible for providing a set of campus-wide network services (e.g. electronic mail) and information technology services outside the university as well as a wide variety of audio, video, and media materials, equipment and services as required by instructional programs, research and administrative areas. The University system has one of the world’s fastest, highest density and advanced wireless computer networks with more than 1400 wireless access points in place. This allows faculty, staff and students to access the campus network and other Internet applications from almost anywhere on campus. As well, by use of a virtual private network and an Internet connection, faculty and students can access all network resources (e.g. library access, databases, class content, course management software) from home or from non-campus computers after authenticating their identities. The PI and other members of the research team use computer services daily, in the form of email and a VPN connection to allow her to connect to the full array of library resources when not on campus. The ITS is knowledgeable and available for consultation on hardware and software that best meets the research team’s needs, and for troubleshooting whenever there is a problem.

The Center for Prevention Research (CPR) is a new CDC-funded (April, 2009) center that provides support for the conduction of research to develop, evaluate, and disseminate health promotion and disease prevention programs in diverse settings and populations, with an emphasis on community-based research and evaluation. In addition, training and education is a critical component of this mission, working to develop behavioral scientists who specialize in health behavior and health promotion and who understand the social and environmental context in which healthy behaviors are developed and maintained. Currently, the Center focuses on five leading health indicators related to lifestyle outlined in Healthy People 2010: Physical Activity and Fitness, Overweight and Obesity, Tobacco Use, Substance Abuse, and Responsible Sexual
Behavior. The CPR has developed some innovative digital data collection methods for their health behavior research. The PI is collaborating with the CPR to make their current data collection methods fully accessible to the visually impaired population she works with.

FRANCES PAYNE BOLTON SCHOOL OF NURSING

The Frances Payne Bolton School of Nursing (Bolton School) is a leader in nursing education and scholarship. The resources available to faculty, staff, and students encompass permanent office suites, state-of-the-art computers, access to technical content experts, library collection that include over 1 million monographs, and the necessary square footage for the conduct of their research and education. The building occupies five levels, two on the lower levels and three above. The School connects via tunnel on this level to other divisions and to University Hospitals of Cleveland. The PI directly benefits from the strong collegial culture of the FPB. In this environment, a high value is placed on sharing knowledge and skills at all levels. Senior researchers share their time and advice freely, actively maintain mentoring relationships with researchers at earlier stages of their careers, and publicly acknowledge and encourage the achievements of all researchers. Junior researchers also collaborate extensively and share their knowledge freely.

The Center of Excellence in Self-Management Research and Translation (SMART Center) is a NIH-funded center in the School of Nursing at Case Western Reserve University that is supported by a strong interprofessional group of researchers with programs of research and expertise in self-management science across several levels of system: individual, family, organization, and community. The SMART Center prepares researchers to extend and disseminate knowledge related to self-management, contribute to the development of emerging biobehavioral research methods, focus on critical issues related to health disparities, and incorporate economic considerations as part of their research. Infrastructure research support services offered by the SMART Center include consultation and mentorship in study design, measurement, economic analysis, statistics, and dissemination of research related to self-management. The SMART Center also includes The FIND Lab (Full Inclusion of Persons with Disabilities), which is developing new tools and strategies to include persons with visual and hearing impairments in research. The resources of the SMART Center will be crucial to the conduct of this self-management research. The PI benefits from consultation and mentorship in study design, measurement, statistics, and dissemination of research. Even more important are the services of the FIND lab. Although issues related to health disparities of people with disabilities are not well recognized in the research community at large, the innovative FIND Lab has been funded to promote inclusion of this population that has been neglected in research. In particular, a strong collaboration with Cleveland Sight Center is enhancing the ability of SMART Center researchers to include visually impaired and blind people fully in their research projects. These methods will be crucial to the success of this particular project, for which all of the research participants will have visual impairment or blindness.

The FPB Center for Research and Scholarship (CFRS) provides infrastructure support for faculty and students with funding opportunities, assists in the development of research proposals including budgeting, editing, and compilation, disseminates research results regionally, nationally, and internationally and assists with post award compliance, budgeting and human subject approval issues. The four full time staff members are dedicated to the support of the research mission of the School of Nursing. They work in conjunction with their counterparts in the centralized University Office of Sponsored Projects Administration to monitor research compliance, budget management and communication with funded projects sponsors. The staff of the CFRS constantly updates the knowledge regarding regulatory changes, compliance issues and funding opportunities so they can provide both faculty and students with the most current guidance. Additionally, the CFRS provides both pre- and post- award consultation and support for investigators including research design, review, human subject training & compliance, and fiscal oversight. Additionally, the CFRS houses a graphical design workshop and printer used for in house preparation and production of scientific posters at no charge to the faculty or students.

THE CLEVELAND SIGHT CENTER
The Cleveland Sight Center is a multi-faceted nonprofit agency that serves people of all ages who are blind or visually impaired. It provides preventative, educational, rehabilitative, and other vision support services directly to approximately 10,000 clients in the greater Cleveland area each year. The Center is accredited by CARF, the Commission on Accreditation of Rehabilitation Facilities. More than 100 specially trained staff members, including social workers, optometrists, certified vision rehabilitation therapists, orientation and mobility instructors, occupational therapists, educators, nurses, and other professionals work to help individuals who are blind or visually impaired. The Center has as its goal to enable the individuals that it serves to reach their full potential at home, school, work and in the community. The services at the Center assist in the development of new skills for personal independence as well as finding employment and training for job advancement. Within the Sight Center is the STORER Center which offers specialized training, orientation, rehabilitation, and electronic resources for individuals who are blind or visually impaired. TheSTORER Center is the Cleveland Sight Center's assistive technology component. It enables individuals who are blind or have low vision to access the high-and-low-technology hardware, software, and Internet tools that people to access information, achieve productivity, and improve their quality of life.

The PI has a well-established relationship with many CSC staff members, and has worked with them on several projects. Most relevant to the current research, she conducted two previous research projects involving CSC clients who have both diabetes and visual impairment: focus groups to learn about their perceptions of their diabetes self-management needs, and a participatory action research project to help meet those needs. Problem-solving and consultation with staff members of Cleveland Sight Center (CSC) has already been valuable in shaping the intervention being explored in this project. CSC's assistance with recruitment of visually impaired participants is crucial to the success of this project. CSC will also help ensure that all diabetes self-management education materials are available in accessible format for the participants. Finally, CSC's highly experienced transportation department will assist with seamless coordination of the transportation needs of participants, all of whom are non-drivers.

THE OHIO COLLEGE OF PODIATRIC MEDICINE
The Ohio College of Podiatric Medicine (OCPM) is one of one of nine medical schools nationwide that specialize in the training of podiatric physicians and surgeons. It is a private, not-for-profit, four-year graduate level medical college, granting the degree of Doctor of Podiatric Medicine. As an independent college of medicine, OCPM has regional and national affiliations with over 50 world-wide hospitals and more than 300 private practitioners nationwide that provide clerkship training to OCPM students. Currently, OCPM maintains an average 4-year school enrollment of 375 students and typically graduates 75-100 podiatrists a year.

The Cleveland Foot and Ankle Institute (CFAI) serves as the clinical teaching and outpatient treatment facility for the Ohio College of Podiatric Medicine. CFAI has been diagnosing and treating the foot and ankle problems of Northeastern Ohio residents for more than 90 years. The podiatric physicians at CFAI comprehensively treat all foot and ankle problems from heel pain, tendinitis, bunions, hammertoes, warts, fungal toenails, and ankle sprains to complex reconstructive surgery, fracture care, infections, and diabetic limb salvage. CFAI's state-of-the-art facilities feature the latest in diagnostic imaging, vascular testing and other comprehensive modalities for the advanced treatment of foot and ankle problems. CFAI has three offices in and around the Cleveland area: Midtown (located in midtown Cleveland), Huron (located at Huron Hospital in East Cleveland), a Cleveland Clinic Hospital, and Independence (located at OCPM). The OCPM is crucial to this project. They will provide 2 key persons for the Research Team: the Project Podiatrist and the Data Monitor. In addition, the CFAI, operated by OCPM and staffed by third year OCPM podiatry students will be the site for gathering baseline and follow-up podiatric assessments.

DIABETES ASSOCIATION OF GREATER CLEVELAND
The Diabetes Association of Greater Cleveland (DAGC), founded in 1954, is Northeast Ohio’s only local and independent diabetes-focused organization and is not affiliated with any national diabetes organization (such as the American Diabetes Association or the Juvenile Diabetes Research Foundation). Its mission is to improve the lives of people with diabetes by leading the Northeast Ohio community in its prevention, management, and cure. DAGC's diabetes educators serve more than 9,000 people annually through
community-wide diabetes education, diabetes self-management education, medical nutrition therapy, risk assessments, emergency diabetes supplies, telephone and online help, and much more. In addition, DAGC owns and operates Camp Ho Mita Koda for children with diabetes in Newbury (Geauga County) and is a large supporter of local diabetes research through its Dietrich Diabetes Research Institute.

DAGC is also key to this project. DAGC staff members who are licensed nurses and dietitians, as well as Certified Diabetes Educators, will provide the Diabetes Self-Management Education for all participants, with the MultiSAFE intervention (experimental group) or usual care (comparison group). DAGC is well-known and trusted in the greater Cleveland community. The PI has a well-established relationship with DAGC, and has worked with DAGC staff members on numerous projects. Most relevant to the current research, DAGC and the PI conducted a participatory action research project in collaboration with clients of CSC who have diabetes and visual impairment. As a result of this project, DAGC has made their diabetes education programs accessible for people with visual impairment, and DAGC staff is already familiar with tools and techniques for working with this population. This makes them a unique resource in the greater Cleveland area for providing the intervention services for this project.
### RESEARCH & RELATED Senior/Key Person Profile (Expanded)

#### PROFILE - Project Director/Principal Investigator

- **Prefix:** [Blank]
- **First Name:** Ann
- **Middle Name:** [Blank]
- **Last Name:** Williams
- **Suffix:** Ph.D.
- **Position/Title:** Research Associate
- **Organization Name:** Case Western Reserve University
- **Department:** Nursing
- **Street:** 10900 Euclid Avenue
- **City:** Cleveland
- **State:** OH, Ohio
- **Country:** USA: UNITED STATES
- **Phone Number:** 216.368.1704
- **Fax Number:** 216.368.5363
- **E-Mail:** ann108@case.edu

#### PROFILE - Senior/Key Person 1

- **Prefix:** [Blank]
- **First Name:** Shirley
- **Middle Name:** [Blank]
- **Last Name:** Moore
- **Suffix:** Ph.D.
- **Position/Title:** Professor of Nursing & Associate Dean for Res
- **Organization Name:** Case Western Reserve University
- **Department:** Nursing
- **Street:** 10900 Euclid Avenue
- **City:** Cleveland
- **State:** OH, Ohio
- **Country:** USA: UNITED STATES
- **Phone Number:** 216.368.5978
- **Fax Number:** 216.368.5363
- **E-Mail:** smm@case.edu

---

[Attachment Details]

**Attach Biographical Sketch:**
- 1245-Williams.pdf
- 1249-Moore.pdf

**Attach Current & Pending Support:**
- [Attachment Details]
### RESEARCH & RELATED Senior/Key Person Profile (Expanded)

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| **Last Name:** Gordon | |  |
| **Title:** Professor | |  |
| **Organization:** Case Western Reserve University | |  |
| **Street:** 10900 Euclid Avenue | |  |
| **City:** Cleveland | |  |
| **State:** OH, Ohio | |  |
| **Country:** USA: UNITED STATES | |  |
| **Phone Number:** 216.368.0726 | |  |
| **Fax Number:** 216.368.5903 | |  |
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**BIOGRAPHICAL SKETCH**

**NAME:**
Williams, Ann S.

**POSITION TITLE:**
Research Associate

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

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<td>BA</td>
<td>1978</td>
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<tr>
<td>Frances Payne Bolton School of Nursing, CWRU, Cleve, OH</td>
<td>BS</td>
<td>1980</td>
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<td>Frances Payne Bolton School of Nursing, CWRU, Cleve, OH</td>
<td>MS</td>
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<tr>
<td>Saybrook Graduate School and Research Center San Francisco, CA</td>
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<td>Postdoctoral Fellowship</td>
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A. **Personal Statement**

I have conducted previous research on the diabetes self-management needs of persons with visual impairment, including both qualitative and quantitative research. I have recently completed a postdoctoral fellowship, during which I focused on strengthening my skills for quantitative research. Although I am only in early stages of a research career, I have had a successful clinical career. I have extensive experience working with persons who have both diabetes and visual impairment, and was the original inventor of the Multi-SAFE intervention. I have actively participated in forming policy of the American Association of Diabetes Educators regarding diabetes self-management education for persons with disabilities. I was the lead author of AADE’s Position Statement on Disabilities in both 2002 and 2009.

B. **Positions and Honors**

**Positions and Employment:**

1981-1982 Staff Nurse, Margaret Wagner House, Cleveland, OH
1983-1986 Volunteer Instructor and Program Coordinator, Church and Community Health Advocacy Program, Cleveland, OH
1986-1987 Nurse Instructor, Inner City Teaching Nursing Home Project, Cleveland, OH
1987-1996 Senior Diabetes Educator, Cleveland Sight Center, Cleveland, OH
1996-1998 Diabetes Educator, Private Practice, Cleveland, OH
1987-2005 Clinical Faculty, Frances Payne Bolton School of Nursing, CWRU, Cleveland, Ohio
2001-2004 Certified Diabetes Educator, USHC Physicians, Inc., Cleveland, OH
2008-2010 Post Doctoral Fellow, Frances Payne Bolton School of Nursing, CWRU, Cleveland, OH
1998-Present Founder and Partner, Diabetes Education Associates, Cleveland, OH
1999-Present Instructor, Dept. of Continuing Education, Cleveland State University, Cleveland, OH
2010-Present Research Associate, Frances Payne Bolton School of Nursing, CWRU, Cleveland, OH

**Professional Memberships:**

American Association of Diabetes Educators
(local chapter: Northeastern Ohio Association of Diabetes Educators)
American Diabetes Association
American Nurses' Association
Diabetes Association of Greater Cleveland
Midwest Nursing Research Society
Sigma Theta Tau
Honors and Awards
1992 Type II Diabetes Award. American Association of Diabetes Educators
1997 Governor's Award. Ohio Affiliate of the American Diabetes Association
1999 Legislative Leadership Award. American Association of Diabetes Educators
1999 Harriett B. Lawrence Scholarship. American Diabetes Association, Heartland Region
2005 Allene Van Son Diabetes Educator Award. Category I, for audiovisual educational tools, for the
recording, Diabetes: the Basics
2005 Allene Van Son Diabetes Educator Award. Category II, for printed educational tools, for the
recording, Living with Diabetes And Visual Impairment, which is in a format that is the equivalent of print for its
intended audience

C. Selected peer-reviewed publications (in chronological order)
1. Williams A. Recommendations for desirable features of adaptive diabetes self-care equipment for visually
2. Williams A. Teaching nonvisual diabetes self-care: choosing appropriate tools and techniques for visually
4. Williams A. Accessible diabetes education materials in low-vision format. The Diabetes Educator
5. International Diabetes Federation, Consultative Section on Diabetes Education. Position statement on
diabetes education for people who are blind or visually impaired. In International Consensus Position
6. Williams A. A focus group study of accessibility and related psychosocial issues in diabetes education for
2004.
9. Williams A. Using Participatory Action Research to Make Diabetes Education Accessible for People with
12. AADE, Williams A, Bartos B, Chynoweth M, Gerwitz A, Kleinbeck C, Lawson V, Shumaker S, & Sokol-
13. Williams A. Universal design in diabetes care: an idea whose time has come. The Diabetes Educator
14. Williams A. Making diabetes education accessible for people with visual impairment. The Diabetes
15. Williams A, Schnarrenberger P. Ensuring valid measurements for a disabled population: an insulin pen pilot

D. Research Support
Ongoing Research Support
3P30NR010676-03S1 (Moore, PI) 9/18/09-8/31/11
NIH/NINR
Full Inclusion of Persons with Disabilities in Self-Management Research
The FIND Lab in the SMART Center of Excellence provides a set of resources and services to researchers
about the use of Universal Design principles to design interventions and their delivery and data collection
methods to support fuller inclusion of people with disabilities in research.
Role: Co-Investigator
Administrative Supplement: Center of Excellence to Build the Science of Self-Management: A Systems Approach, Core Consolidation for Behavioral Science Measurement Lab

In this project three existing measurement cores on the Case Western Reserve University Campus will be consolidated to create one full-service, easy access, high-profile support for behavioral research measurement.

Role: Co-Investigator

Grant

Nonvisual Foot Inspection for People with Visual Impairment

The purpose of this study is to find out whether a method of nonvisual foot inspection, using the senses of touch and smell, helps people with diabetes and visual impairment to find new foot problems when they are in early, easily-treated stages.

Role: Principle Investigator

Recently Completed Research Support

T32-NR009761 (Moore, PI)

NIH/NINR

Multiple Morbidities in Vulnerable Populations: Nurse Scientist Training

The proposed predoctoral and postdoctoral training program provides research training for nurses pursuing research careers focused on vulnerable populations with multiple morbidities.

Audio Instruction for the Use of Insulin Pens by Blind People

Research Award

Role: Principle Investigator

Use of Insulin by blind people: a feasibility study.

Supported by the

2008
BIOGRAPHICAL SKETCH

NAME
Moore, Shirley M.

POSITION TITLE
Edward J. and Louise Mellen Professor of Nursing and Associate Dean for Research

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

<table>
<thead>
<tr>
<th>INSTITUTION AND LOCATION</th>
<th>DEGREE (if applicable)</th>
<th>YEAR(S)</th>
<th>FIELD OF STUDY</th>
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<tbody>
<tr>
<td>Kent State University, OH</td>
<td>BSN</td>
<td>1974</td>
<td>Nursing</td>
</tr>
<tr>
<td>Case Western Reserve University, OH</td>
<td>MSEd</td>
<td>1979</td>
<td>Education</td>
</tr>
<tr>
<td>Case Western Reserve University, OH</td>
<td>MSN</td>
<td>1990</td>
<td>Nursing</td>
</tr>
<tr>
<td>Case Western Reserve University, OH</td>
<td>PhD</td>
<td>1993</td>
<td>Nursing</td>
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</table>

A. Personal Statement
As Director of a P30 Center of Excellence in Self-Management Research, I will provide knowledge of current literature and approaches for research addressing self-management of health, which is the focus of this proposal. I have considerable experience designing and testing interventions for patient self-management and have served as Principal Investigator of several NIH-funded studies with this focus. My program of research has focused on the design and test of interventions to promote healthier living of persons with chronic disease. Those experiences should all be useful in my role as co-investigator on this project. Lastly, as the director of our FIND Lab (Full INclusion of Persons with Disabilities in Self-Management Research), I offer the full support of our services to the research team to make modifications in the research protocol to accommodate persons with disabilities, in this case, particularly those related to sight. Dr. Williams and I work collaboratively on the FIND Lab project and several supplements to this project and thus will continue our work with populations with special needs in this project.

B. Position and Honors

Positions and Employment
1969-1971 Staff Nurse, Coronary and Cardiac Intensive Care, The Mt. Sinai Hospital of Cleveland, Cleveland, OH
1971-1972 Head Nurse, Coronary and Cardiac Intensive Care, The Mt. Sinai Hospital of Cleveland
1976-1981 Director, Continuing Education Department, The Mt. Sinai Hospital of Cleveland
1982-1984 Director, Nursing Education, The Cleveland Clinic Foundation, Cleveland, OH
1984-1987 Director, Nursing Resources, The Cleveland Clinic Foundation, Cleveland, OH
1987-1990 Research Assistant, Case Western Reserve University, Cleveland, OH
1990-1992 Grant Project Director, Case Western Reserve University, Cleveland, OH
1992-1998 Assistant Professor, School of Nursing, Case Western Reserve University, Cleveland, OH
1998-2004 Associate Professor, School of Nursing, Case Western Reserve University, Cleveland, OH
2001-present Associate Dean for Research, School of Nursing, Case Western Reserve University
2002-present Faculty Associate, University Center on Aging and Health, Case Western Reserve University
2003-present Faculty Associate, Center for Health Promotion Research, Case Western Reserve University
2004-present Professor, School of Nursing, Case Western Reserve University

Honors and Professional Activities
1997 Finalist, New Investigator Award, American Heart Association, Council on Cardiovascular Nursing
1997 Fellow, National Academy of Practice in Nursing, National Academies of Practice
1998 Fellow, American Heart Association, Council on Cardiovascular Nursing
2000- Risk Prevention and Health Behavior Review Panel, NIH, Reviewer, Initial Review Group Study Section
2002 Distinguished Contribution to Nursing Research, Acute Care Nursing Section, Midwest Nursing Research Society
2002 Fellow, American Academy of Nursing
2005 Crain's Cleveland Business' Who's Who in Technology for 2005
2006 Edward J. and Louise Mellen Endowed Professorship
2007 Ada Sue Hinshaw Award, Friends of the National Institute of Nursing Research
2003  Competence in Aging Award, American Heart Association Council on Cardiovascular Nursing
2009  John A. Hartford/MNRS Award for Leadership in Geriatric Nursing Research, Midwest Nursing Research Society
2010  Inaugural Inductee, International Nurse Researcher Hall of Fame

C. Publications (selected from 90)
   Most relevant to the current application
coronary artery bypass surgery. Research in Nursing and Health, 24 (2), 93-104.
   2. Dolansky, M.A., Moore, S.M. (2003). Disability and rehabilitation services in older adults following
   exercise maintenance following cardiac rehabilitation. Journal of Cardiopulmonary Rehabilitation, 23
   (1), 40-49.
   Effects of a CHANGE intervention to increase exercise maintenance following cardiac events. Annals
   of Behavioral Medicine, 31(1), 53-62.
   Journal of the American Academy of Nurse Practitioners, 18(12), 559-565.
   Journal of Nursing Research, 30(2), 163-160.
   increasing family social support. Annals of Behavioral Medicine, 39, S154.
   services received by older adults following a cardiac event: A population-based analysis. Journal of
   Cardiovascular Nursing, 25(4), 342-349.

Additional recent publications of importance to the field (in chronological order)
    adoption and maintenance of exercise following cardiac events. Circulation (supplement), 106 (19),
    11664.
    house calls to Medicare beneficiaries. Journal of the American Medical Association, 294(19),
    2435-2436.
    Moving from deficit models to affirmation models of care. Family and Community Health, Supplement
    30(1), S64-S74.
    event. Rehabilitation Nursing 33(2), 73-81.
    to increase physical activity among cardiac subjects. International Journal of Cardiology, 133, 307-320.
15. Miller, DM, Fox, R., Atreja, A., Moore, S., Lee, J-C, Fu, A.Z., Jain, A., Saupe, W., Chakraborty,
    Study Sample of Multiple Sclerosis Patients. Telemedicine and e-Health, 16 (1): 63-68.
D. Research Support

Ongoing

1U01 HL103622-01 (Borawski/Cutler/Moore, Co-PI's) 08/17/2010-04/30/2017
NIH/NHLBI

Targeting Obesity and Blood Pressure in Urban Youth
This 3-group randomized clinical trial will test the effect of a multi-level intervention (community, school, and family) on blood pressure and BMI in children in grades 6-8 in the Cleveland Metropolitan School District.

P30NR010676 (Moore, PI) 09/29/07-06/30/12
NIH/NINR

Center of Excellence to Build the Science of Self-Management: A Systems Approach
The SMART Center will prepare a critical mass of researchers to extend and disseminate knowledge related to self-management.

3P30NR010676-03S1 (Moore, PI) 09/16/09-08/31/11
NIH/NINR

Full Inclusion of Persons with Disabilities in Self-Management Research
The FIND Lab in the SMART Center of Excellence provides a set of resources and services to researchers about the use of Universal Design principles to design interventions and their delivery and data collection methods to support fuller inclusion of people with disabilities in research.

P30NR010676 - 04S1 (Moore, PI) 9/29/10-9/28/11
NIH/NINR

Administrative Supplement: Center of Excellence to Build the Science of Self-Management: A Systems Approach, Core Consolidation for Behavioral Science Measurement Lab
In this project three existing measurement cores on the Case Western Reserve University Campus will be consolidated to create one full-service, easy access, high-profile support for behavioral research measurement.

5R01 HL084767 (Moore, PI) 07/10/06-03/31/11
NIH/HLBI

Improving Long-term Exercise in Older Cardiac Patients
The aims of this study are to conduct a head-to-head evaluation of the effects of two theoretically different interventions (SystemCHANGE and CHANGE+) on lifestyle exercise following a cardiac event.

1R01CA127493-01A2 (Pl: Zhang) 1/1/09-11/30/12
NIH/NCI

Improving Urinary Continence and Quality of Life in Prostate Cancer Patients
To test the intervention effect of biofeedback trained Pelvic Floor Muscle Exercises (PFME) combined with support groups on urinary incontinence and health related quality of life in men with prostate cancer.
Role: Co-Investigator

5UL1 RR024989 (Davis, PI) 09/17/07-05/31/12
NIH

Institutional Clinical and Translational Science Award (CTSA)
The purpose of this grant is to coordinate existing resources relevant to clinical research at Case Western Reserve University and three of its hospital affiliates.
Role: Co-Director, Education Core

T32 NR 009761 (Moore, PI) 05/18/06-04/30/11
NIH/NINR

Multiple Morbidities in Vulnerable Populations: Nurse Scientist Training
The proposed predoctoral and postdoctoral training program provides research training for nurses pursuing research careers focused on vulnerable populations with multiple morbidities.
BIOGRAPHICAL SKETCH

NAME
Aron, David

POSITION TITLE
Professor

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

<table>
<thead>
<tr>
<th>INSTITUTION AND LOCATION</th>
<th>DEGREE (If applicable)</th>
<th>MM/YY</th>
<th>FIELD OF STUDY</th>
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<tr>
<td>Columbia College, New York City</td>
<td>BA</td>
<td>1971</td>
<td>Political Science</td>
</tr>
<tr>
<td>Columbia College of Physicians/Surgeons, NYC</td>
<td>MD</td>
<td>1975</td>
<td>Medicine</td>
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<tr>
<td>University of California, San Diego, CA</td>
<td>Resident</td>
<td>1979</td>
<td>Internal Medicine</td>
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<tr>
<td>University of California, San Francisco, CA Metabolic Research Unit</td>
<td>Fellow</td>
<td>1980</td>
<td>Endocrinology</td>
</tr>
<tr>
<td>University of Michigan, Ann Arbor, MI</td>
<td>MS</td>
<td>1995</td>
<td>Clinical Research Design &amp; Statistical Analysis</td>
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</table>

A. Personal Statement
The goal of the proposed research is to develop and test methods for nonvisual foot self-examination, a novel self-management technique designed to promote better foot care for people with visual impairment. I have been an endocrinologist, providing care for patients with diabetes for over 25 years. Similarly, I have been involved in research and have had independent funding for over 25 years. I have also been involved in the assessment and improvement of diabetes care delivery. Specifically, I have studied the impact of amputations in diabetes, developed measures of quality of diabetes care, and have been involved in the development and assessment of new models of diabetes care. I have been a mentor for young investigators for many years. Many of them have gone on to obtain independent funding. Others have become leaders in quality improvement. In summary, I have a demonstrated record of successful and productive research projects in an area of high relevance for diabetes self-management, and my expertise and experience have prepared me to be a co-investigator and mentor for this project.

B. Positions and Honors

Academic Appointments:
1980-1987 Asst. Prof. of Med, Case Western Reserve Univ. (CWRU) School of Medicine, Cleveland, OH
1987-1993 Associate Professor of Medicine, CWRU School of Medicine
1993-present Professor of Medicine, CWRU School of Medicine
1997-present Professor, Department of Epidemiology and Biostatistics, CWRU
2004-present Professor, Dept. of Organizational Behavior, Weatherhead School of Management, CWRU

Clinical/Administrative Appointments:
1982-present Staff Physician, V.A. Medical Center, Cleveland, OH
1986-1990 Chief, Endocrinology Section, V.A. Medical Center, Cleveland, OH
1991-1996 Associate Chief, Medical Service, V.A. Medical Center, Cleveland, OH
1996-1998 Acting Chief, Medical Service, VA Med Ctr, and Interim Vice Chairman, Dept of Med, CWRU
1998-present Senior Scholar, VA Quality Scholars Fellowship Program
1999-present Assoc. Chief of Staff/Education, Louis Stokes Cleveland DVA Medical Center, Cleveland, OH
2002-present Chair, Diabetes/Endocrine Field Advisory Committee, Dept. of Veterans Affairs
2002-present Member, Executive Committee, QUERI-DM Center, Dept. of Veterans Affairs
2006-present Co-Clinical Coordinator, QUERI-DM Center, Dept. of Veterans Affairs
2009-present Co-Director, QUERI Center for Implementation Practice and Research Support (CIPRS)

Honors:
1975 Alpha Omega Alpha
1983 Teacher of the Year - Dept. of Medicine
1989 Student Committee on Medical Education Award for Outstanding Teaching
1991 Kaiser-Permanente Award for Excellence in Teaching
2007 David M. Worthen Award for Academic Excellence, Dept. of Veterans Affairs.
2007-2010 Best Physicians in America
C. Selected Peer-reviewed Publications (Selected from 163 peer-reviewed publications)

Most relevant to the current application


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


D. Research Support

Ongoing Research Support

EDU 08-414 (Kirsh, PI) 10/01/09-09/30/12

VA HSR&D

Interprofessional Training to Improve Diabetes Care: The ReSPECT Trial

Goals: Improving the care of diabetes, a complex chronic illness, by providing important insights into interprofessional training and its potential role in fostering the necessary interdisciplinary management
needed for chronic conditions and in addressing the gap between best practice and actual care provided.
Role: Co-I and Mentor for the PI

RRP 09-167 (Aron, PI) 04/01/10-03/31/11
VA HSR&D
**Identifying Potentially Better Practices for Outpatient Diabetes Care**
Goals: To identify high performing sites and identify the practices they utilize – “best practices” – in order that these practices be shared with other sites. In so doing, we will contribute to a national effort in diabetes care systems redesign.

RRP 09-165 (Kirsh, PI) 04/01/10-03/31/11
VA HSR&D
**Identifying Best Practices to Reduce Hypoglycemia in ICUs**
To inform best practices for inpatient hypoglycemia that occurs outside the confines of the ICU and is part of the QUERI-DM strategic goal of improving care systems for diabetes and has been so endorsed.
Role: Co-I

TRA 08-379 (Mittman, PI) 10/01/08-09/30/12
VA HSR&D
**Quality Enhancement Research Initiative (QUERI) Center for Implementation Practice and Research Support**
Goals: Goal 1) Activities will strengthen and support the capacity and activities of VA implementation researchers as they work with VA operations programs to achieve improvements in performance. 2) In contrast, represents a more direct form of C-IRIS contribution to improvements in VA quality and performance in that Goal 2 entails direct support for VA operations programs' implementation activities. 3) Will involve a smaller volume of activity offering indirect contributions to VA policy and practice goals. Goal 3 will support QUERI program leadership and its efforts to strengthen QUERI and VA implementation research.
Role: Co-Director

IIR 02-225 (Kerr, PI) 1/1/2004-12/31/2010
VA HSR&D
**Addressing Barriers to Translation for Treatment of Hypertension (ABATE)**
The goals of this project are to define important clinician, organizational and patient factors that contribute to clinical inertia in the treatment of hypertension; and design appropriate quality improvement (QI) interventions that address the most important barriers and facilitators to translation for high risk patients with hypertension.
Role: Site-PI

IIR-07-185-01(Piette, PI) 07/01/08-06/30/12
VA HSR&D
**Enhancing Informal Caregiver Support for Heart Failure**
The goals of this project is to randomized trial is to evaluate the impact of extending the reach of health information technology by incorporating a protocol-driven model for improved monitoring and self-management support by a CarePartner (CP).
Role: Co-I

**Completed Research Support**
IIR 03-254 (Aron, PI) 04/01/05-08/31/09
VA HSR&D
**Diabetes Telemedicine Consultation: A Systems Improvement Intervention**
(1) Compare the impact of diabetes specialist joint-clinic consultations via teleconferencing conducted at CBOCs to the usual consultation process on referred high-risk patients and providers; (2) Compare the impact of diabetes specialist joint-clinic consultations via teleconferencing conducted at CBOCs to the usual consultation process on non-referred patients receiving care at the CBOCs; (3) Compare processes and change in processes associated with diabetes specialist joint-clinic consultations to usual outpatient
consultation process for patients with diabetes using qualitative and quantitative methods (microsystem factors).

SHP 08-194 (Aron, PI) 06/01/09-12/31/09
VA HSR&D
Short term project- Developing PBLI QI-Systems Impact Assessment Tool for Residents
Goal is to enable physicians to assess care and to make quality improvements. Analyses of the data collected will provide assessment of the impact of the curriculum on residents and the organization.

SHP 08-191 (Aron, PI) 06/01/09-12/31/09
VA HSR&D
Short term project- Improving Medical Training for the Care of Chronic Conditions
Goal is to improve quality care that we provide Veterans with chronic conditions, in general, and diabetes specifically. SMAs are proving to be a successful approach to the delivery of quality chronic illness care. It is essential that we understand all the ways that SMAs improve diabetes management, including through linking quality training to quality care.

DIT 02-064 (Bernstein, PI) 01/01/2004-12/31/2009
VA HSR&D
Evaluation of a Coordinated Proactive Diabetes Eye Care Program (I-Care)
The major goal of this project is to investigate how to improve the care of veterans with diabetes by providing coordination of scheduling for eye care services.
Role: Site-PI
BIOGRAPHICAL SKETCH

NAME
Gordon, Nahida H.

POSITION TITLE
Professor

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

<table>
<thead>
<tr>
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<th>DEGREE (if applicable)</th>
<th>YEAR(s)</th>
<th>FIELD OF STUDY</th>
</tr>
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<tbody>
<tr>
<td>University of Cincinnati, Cincinnati, OH</td>
<td>BS</td>
<td>1961</td>
<td>Mathematics</td>
</tr>
<tr>
<td>University of Wisconsin, Madison, WI</td>
<td>MS</td>
<td>1962</td>
<td>Mathematics</td>
</tr>
<tr>
<td>Case Western Reserve University (CWRU), Cleveland, OH</td>
<td>PhD</td>
<td>1980</td>
<td>Probability &amp; Statistics</td>
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</table>

A. Personal Statement
I will contribute my expertise in evaluation of outcomes research and multivariate modeling. I have extensive experience as a biostatistician for NIH-funded projects related to communication, longitudinal outcomes, and intervention studies. I will take the lead in all areas of statistical analysis in the study. I also have a well-established record of scholarly productivity and will contribute to the conceptualization, analysis and writing of manuscripts that will result from this project.

B. Positions and Honors

Positions and Employment (Selected)
1994-1998 Director, Biostatistics Graduate Studies, Dept. of Epidemiology and Biostatistics, School of Medicine, CWRU, Cleveland, OH
2001-2002 Professor, Dept. of Epidemiology and Biostatistics, School of Medicine, CWRU, Cleveland, OH
2001-2005 Professor, Department of Bioethics, School of Medicine, CWRU, Cleveland, OH
2005-Present Professor, secondary appointment, Department of Bioethics, School of Medicine, CWRU, Cleveland, OH
2005-Present Professor, Frances Payne Bolton School of Nursing, CWRU, Cleveland, OH

Honors and Awards
1995 AIBS Gulf War Syndrome Epidemiology Review Panel
1995 NIH Cancer Prevention and Control Research Small Grant Program
1996 NIH Program Project Review Panel in Breast Cancer
1996 NIH Epidemiology Section 2, special requested review of breast cancer proposal
1997 NIH Program Project Review Panel in Breast Cancer
1993-2001 NIH/DRG Epidemiology and Disease Control EDC-2 Study Section
1995 NIH Cancer Center Review Panel, Ad hoc
Fulbright Senior Scholar, Phi Beta Kappa, MS with honors, BS with honors, Alpha Lambda Delta

Other Experience and Professional Memberships (Selected)
1995 AIBS Gulf War Syndrome Epidemiology Review Panel
1995 NIH Cancer Prevention and Control Research Small Grant Program
1996 NIH Program Project Review Panel in Breast Cancer
1996 NIH Epidemiology Section 2, special requested review of breast cancer proposal
1997 NIH Program Project Review Panel in Breast Cancer
1998-2001 NIH/DRG Epidemiology and Disease Control EDC-2 Study Section

C. Selected peer-reviewed publications


C. Research Support

Ongoing Research Support

R01 HL085725 (Madigan, PI) 04/01/07-02/28/11
NIH/NHLBI
Effects of Home Care Agency Providers and Visits on Heart Failure Patient Outcomes
This study will examine re-hospitalization and functional status decline in home health care patients with heart failure using individual, provider and market factors for a national population of home health care patients from 2005.
Role: Co-Investigator

R01 HL09676 (Hughes/Dolansky, Co-Pls) 04/5/10-01/31/14
NIH
Self-management and Cognitive Impairment in Adults with Heart Failure
The purpose of this study is to assess the relationship between cognitive impairment, patient self-management, health, and health service use in adults with heart failure.
Role: Co-Investigator

2 R01 NR005067 (Musil, PI) 09/05/06-12/31/10
NIH/NINR
Grandmothers, Caregiving, Families, and Transitions
The specific aims of this continuation study are to: 1) extend the evaluation of the grandmother caregiving experience across time; 2) evaluate grandchildren’s perceptions of family functioning, support and depressive
symptoms and compare these data with data from the grandmother, and 3) examine the effects of caregiving transitions on grandchildren, and 4) identify perceived needs for interventions.

Role: Co-Investigator

**RO1 NR010787 (Daly, PI) **
09/01/07-05/31/11
NIH/NINR

**Improving the Quality of Advanced Cancer Care with Disease Management**
Despite wide-spread efforts, patients with advanced cancer and their families continue to identify shortcomings in end of life care. The purpose of this investigation is to implement a comprehensive disease management program (DMP) and measure effects on quality of care and health related quality of life of advanced cancer patients and their families, and to examine the cost effectiveness of such a program.

Role: Co-Investigator

**R01CA127493-01A2 (PI: Zhang) **
01/01/09-11/30/12
NIH/NCI

**Improving Urinary Continence and Quality of Life in Prostate Cancer Patients**
The objective of this study is to test the intervention effect of biofeedback trained Pelvic Floor Muscle Exercises (PFME) combined with support groups on urinary incontinence and health related quality of life in men with prostate cancer.

Role: Co-Investigator

**1R21NR010781-01 (Winkelman, PI) **
05/01/09-04/30/11
NIH/NINR

**Dose of Early Therapeutic Mobility: Does Type or Frequency of Activity Matter?**
This innovative study will examine the impact of ETM activity on inflammatory biomarkers in adults receiving mechanical ventilation. It investigates for the first time the affect of passive range of motion and orthostatic conditioning on recovery in patients in the intensive care unit.

Role: Co-Investigator

**T32 NR009761 (Moore, PI) **
05/18/06-04/30/11
NIH/NINR

**Multiple Morbidities in Vulnerable Populations**
This pre-doctoral and postdoctoral training program provides research training for nurses pursuing research careers focused on vulnerable populations with multiple morbidities.

Role: Co-Investigator

**1P30NR010676-01 (Moore, PI) **
09/29/07-05/30/12
NIH/NINR

**Center of Excellence to Build the Science of Self-Management: A Systems Approach**
The SMART Center will prepare a critical mass of researchers to extend and disseminate knowledge related to self-management, contribute to the development of emerging biobehavioral research methods, focus on critical issues related to health disparities, and incorporate economic considerations as part of their research.

Role: Statistician

**R01 AG034157 (Figueroio, PI) **
05/01/10-04/30/14
NIH/NIA
Rensselaer Polytechnic Institute

**Methodology Issues in a Tailored Light Treatment for Persons with Dementia**

Role: Co-Investigator

**5R01 HL064767 (Moore, PI) **
07/10/06-03/31/11
NIH/NHLBI

**Improving Long-term Exercise In Older Cardiac Patients**
SystemCHANGE, a novel intervention that focuses on environmental change uses System Improvement strategies to increase exercise, will be compared to CHANGE+ (an intervention based on contemporary cognitive behavioral strategies).

Role: Co-Investigator
Recently Completed Research Support

R15 NR009797 (Dallato, PI) 04/01/07 - 03/31/10
NIH/NINR

Sleep Patterns and Depression in Mothers and Fathers of Twins
The proposed project will examine relationships between sleep and depression and fatigue in mothers and fathers of twins and identify useful strategies to be tested in a future study to minimize sleep loss and its adverse effects.
Role: Statistician

RO1 HL085725-01A1 (Madigan, PI) 04/01/07 - 02/28/10
NIH/NHLBI

Effects of Home Care Agency Providers and Visits on Heart Failure Patient Outcomes
This study will examine re-hospitalization and functional status decline in home health care patients with heart failure using individual, provider and market factors for a national population of home health care patients from 2005. Role: Co-Investigator

R01 NR008941 (Daly, PI) 08/01/05 - 07/31/09
NIH/National Institute of Nursing Research

Intensive Communication for Chronically Critically Ill
The specific aims of this proposal are to examine the effect of implementing an intensive communication system (ICS) on chronically critically ill patient and family outcomes and resource use in ICUs.
Role: Co-Investigator

VA HSR&D (Aron, PI) 04/01/05 - 03/31/09

Diabetes Telemedicine Consultation: A Systems Improvement Approach
The overall immediate objective is to evaluate and document the processes of outreach consultation through using joint-clinics via teleconferencing as an intervention for system improvement in care delivery and management of diabetes at CBOCs.
Role: Co-Investigator

SBE-0245054 (Singer, PI) 07/03/03 - 08/31/08
NSF

ACES: ADVANCE Institutional Transfer
Role: Biostatistician
BIOGRAPHICAL SKETCH

NAME
Caldwell, Bryan D

POSITION TITLE
Professor and Dean of Clinical Education

eRA COMMONS USER NAME (credential, e.g., agency login)

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

<table>
<thead>
<tr>
<th>INSTITUTION AND LOCATION</th>
<th>DEGREE</th>
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<th>FIELD OF STUDY</th>
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<tr>
<td>University of South Florida, Tampa, FL</td>
<td>B.A.</td>
<td>05/85</td>
<td>Natural Sciences/Biology</td>
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<tr>
<td>Ohio College of Podiatric Medicine, Cleveland, OH</td>
<td>D.P.M</td>
<td>05/89</td>
<td>Podiatric Medicine</td>
</tr>
<tr>
<td>Florida Hospital East Orlando, Orlando, FL</td>
<td>Residency</td>
<td>06/91</td>
<td>Podiatric Medicine &amp; Surgery</td>
</tr>
<tr>
<td>University of Notre Dame, Notre Dame, IN</td>
<td>M.S.</td>
<td>08/94</td>
<td>Molecular Biology</td>
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A. Personal Statement
People with visual impairment are underrepresented in diabetes self management education research. Evidence-based medicine offers scant guidance regarding effective self-management for these patients. As a podiatric physician, I see a large number of patients with diabetes mellitus and offer preventive foot and lower extremity care to them daily. Unfortunately, those patients with visual impairments are unable to perform many existing preventive care regimens due to their loss of sight. These patients are therefore more likely to suffer consequences including infections and amputations. My background is diverse in the field of podiatric medicine and surgery. In medical school, I had a special interest in diabetes and infectious diseases so I therefore traveled to the University of Texas at San Antonio to complete a fellowship in cardiology for its excellence in the treatment of the diabetic foot. Diabetes mellitus is prevalent in this area of the country. I graduated as Valedictorian of my class of 112 students and then completed my residency at Florida Hospital. I have treated thousands of patients with diabetes mellitus throughout my career, cognizant to the fact that preventive medicine plays a most vital role in this population. I also serve as a staff podiatrist for the Louis Stokes VA Hospital, OH, and several geriatric centers. Many of these patients suffer foot problems secondary to diabetes mellitus and many have visual impairment to some degree.

B. Positions and Honors

Positions and Employment
1991-1992 Private Practice, Westside Foot and Ankle Clinic, Jacksonville, Florida
1994-1999 Assistant Professor, Ohio College of Podiatric Medicine
1995-1999 Residency Director, University Hospital Richmond Heights Medical Center
1997 Board Certification, American Board of Podiatric Orthopedics and Primary Medicine
1999-2004 Associate Professor, Ohio College of Podiatric Medicine
1999-2002 Residency Director, Cleveland Clinic Foundation/OCPM
2000-2002 Fellow, Physician Executive Leadership Program, Case Western Reserve University School of Medicine
2001-2002 Assistant Clinical Director of Operations and Education, Ohio College of Podiatric Medicine
2002-2006 Residency Director, University Hospital Richmond Heights Medical Center
2002-2009 Assistant Dean of Clinical Education, Ohio College of Podiatric Medicine
2007-2009 Department Chairman of Podiatric Medicine, Ohio College of Podiatric Medicine
2007 Board Re-Certification, American Board of Podiatric Orthopedics and Primary Medicine
1997-present Staff Podiatrist, Louis Stokes Cleveland Department of Veterans Affairs Medical Center
2004-present Professor, Ohio College of Podiatric Medicine
2009-present Dean of Clinical Education and Operations, Ohio College of Podiatric Medicine
### Honors

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<td>1982</td>
<td>University of South Florida Entrance with Honors Certification</td>
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<td>1982</td>
<td>Scottish Rite Academic Scholarship</td>
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<td>Civitan Club of Jacksonville Academic Scholarship</td>
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<td>1982</td>
<td>University of South Florida Academic Scholarship</td>
</tr>
<tr>
<td>1982</td>
<td>Themis Honor Society inductee, University of South Florida</td>
</tr>
<tr>
<td>1982</td>
<td>University of South Florida Dean's List</td>
</tr>
<tr>
<td>1983</td>
<td>University of South Florida Dean's List</td>
</tr>
<tr>
<td>1984</td>
<td>University of South Florida Dean's List</td>
</tr>
<tr>
<td>1984</td>
<td>University of South Florida Superior Academic Achievement Award</td>
</tr>
<tr>
<td>1985</td>
<td>University of South Florida Dean's List</td>
</tr>
<tr>
<td>1986</td>
<td>OCPM Academic Scholarship</td>
</tr>
<tr>
<td>1987</td>
<td>OCPM Academic Scholarship</td>
</tr>
<tr>
<td>1988</td>
<td>Pi Delta Honor Society inductee</td>
</tr>
<tr>
<td>1988</td>
<td>OCPM Academic Scholarship</td>
</tr>
<tr>
<td>1989</td>
<td>Harvey Haber Memorial Award for Proficiency in Clinical Diagnosis</td>
</tr>
<tr>
<td>1989</td>
<td>Baird Johnson Memorial Award for Service to Institution and Classmates</td>
</tr>
<tr>
<td>1989</td>
<td>OCPM Valedictorian Award</td>
</tr>
<tr>
<td>1995</td>
<td>OPMPSA President's Award for Loyal Service to the College and Podiatry</td>
</tr>
<tr>
<td>1996</td>
<td>AGK Award in Recognition of Superior Performance and Dedicated Service</td>
</tr>
<tr>
<td>1996</td>
<td>OPMPSA President's Award for Loyal Service to the College and Podiatry</td>
</tr>
<tr>
<td>1996</td>
<td>Who's Who Among America's Teachers</td>
</tr>
<tr>
<td>1996</td>
<td>OCPM Sports Medicine Club Appreciation Award</td>
</tr>
<tr>
<td>1996</td>
<td>Faculty Member of the Year Award</td>
</tr>
<tr>
<td>2003</td>
<td>Ohio Magazine Excellence in Education</td>
</tr>
</tbody>
</table>

### C. Selected Peer-reviewed Publications

**Most relevant to the current application**


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


D. Research Support

**Ongoing Research Support**

<table>
<thead>
<tr>
<th>Private Source</th>
<th>Grant</th>
<th>8/30/2010 - 8/29/2012</th>
</tr>
</thead>
</table>

**Nonvisual Foot Inspection for People with Visual Impairment**
The purpose of this study is to find out whether a method of nonvisual foot inspection, using the senses of touch and smell, helps people with diabetes and visual impairment to find new foot problems when they are in early, easily-treated stages.  
Role: Co-Investigator

<table>
<thead>
<tr>
<th>Private Source</th>
<th>(Caldwell, PI)</th>
<th>2009-2010</th>
</tr>
</thead>
</table>

**A Prospective, Randomized Blinded Multicenter, Parallel Study Comparing Transdermal, Continuous Oxygen Delivery to Moist Wound Therapy (MWT) in the Treatment of Diabetic Foot Wounds**
The goal of this study is to determine if there is a difference in the number of wounds healed within 12 weeks between those receiving transdermal continuous oxygen and those receiving moist wound therapy only.

<table>
<thead>
<tr>
<th>Private Source</th>
<th>(Caldwell, PI)</th>
<th>2005-2009</th>
</tr>
</thead>
</table>

**Completed Research Support**

**The Value of Podiatrists Offering a Walking Prescription**
The main goal of the project was to observe benefits of different exercise prescriptions given by podiatric physicians.
BIOGRAPHICAL SKETCH

NAME
Kawalec-Carroll, Jill Suzanne

POSITION TITLE
Director of Research
Assistant Professor, Dept. of Basic Sciences

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

<table>
<thead>
<tr>
<th>INSTITUTION AND LOCATION</th>
<th>DEGREE (if applicable)</th>
<th>MM/YY</th>
<th>FIELD OF STUDY</th>
</tr>
</thead>
<tbody>
<tr>
<td>University of Pennsylvania, Philadelphia, PA</td>
<td>B.S.</td>
<td>05/91</td>
<td>Biomedical Engineering</td>
</tr>
<tr>
<td>Case Western Reserve University, Cleveland, OH</td>
<td>M.S.</td>
<td>01/94</td>
<td>Biomedical Engineering</td>
</tr>
<tr>
<td>Case Western Reserve University, Cleveland, OH</td>
<td>Ph.D.</td>
<td>01/97</td>
<td>Biomedical Engineering</td>
</tr>
</tbody>
</table>

A. Personal Statement

The goal of the proposed research is to evaluate the effects of teaching a method for nonvisual foot inspection to people with diabetes and visual impairment, using the senses of touch and smell. A portion of the research proposes to conduct a study to determine how often the study participants inspect their feet and whether or not doing nonvisual foot inspection helps them to discover foot problems in early stages, when the problems are easier to treat. I have the experience and motivation necessary to successfully complete my role as data monitor in the proposed research. I have a background in Biomedical Engineering, and a good knowledge of podiatric medicine due to more than 13 years as Director of Research at the Ohio College of Podiatric Medicine (OCPM). I have significant experience in writing grant proposals, performing research, collecting and analyzing data, and writing final reports and manuscripts. As Director of Research, I collaborate regularly with OCPM faculty members from the Departments of Podiatric Medicine, Podiatric Surgery and Orthopedics. I also advise both faculty, residents in podiatric medicine and students at OCPM on developing research plans and proposals. Throughout my career, I have participated in various clinical trials and studies as a study coordinator, including various multicenter wound healing studies. I have also completed a 50-hour online program on monitoring clinical trials, with a grade of 99% on the final examination. As a result of these previous and current experiences, I am qualified and prepared to serve as the data monitor for the proposed research.

B. Positions and Honors

Positions and Employment

1996-present Director of Research/Assistant Professor, Dept. of Basic Sciences, Ohio College of Podiatric Medicine, Independence, OH
1998-present Adjunct Assistant Professor, Dept. of Biomedical Engineering, Case Western Reserve University, Cleveland, OH

Additional Training

April, 2009 Monitoring Clinical Studies – Completed with a 99% grade in the final exam. The Clinical Research Training program, Monitoring Clinical Studies is a 50-hour online program accredited by PA Nursing Association for 48 Contact Hours. The course consists of four modules. The first module discusses the Drug Development Process, which includes FDA Regulations, ICH Guidelines and HIPAA as they pertain to the Monitoring of Clinical Studies. The other three modules consist of the initiation of a Study, Monitoring the Study and Closing the Study. Good Clinical Practice and Standard Operating Procedures are also covered. Monitoring Clinical Studies is equivalent to a week and a half of classroom training. Clinical Research Training Online, Inc. provided this training program.

June, 2010 Statistics for Clinical Research – Completed the course and passed the course mastery exam. Statistics for Clinical Research is a 25-30 hour online training program designed to teach the statistical principals for designing and analyzing clinical trials. This course covers such topics
as the different types of study data, measuring variance, statistical concepts and tests, sample size calculation and interpretation of study results.

Other Experience and Professional Memberships

1990-2000 Member, Pediatric Research Society (now defunct)
1998-1999 Member, American Association for Laboratory Animal Science
1996-present Member, Society For Biomaterials
2000-present Fellow, International Cartilage Repair Society (named Fellow in 2008)
2007-present Non-Affiliated Scientific Member (Without Compensation), Institutional Animal Care and Use Committee (IACUC), Louis Stokes Cleveland Department of Veterans Affairs Medical Center

Honors

1990 National Science Foundation-Research Experience for Undergraduates Fellowship
1996 Graduate Dean’s Instructional Excellence Award

C. Selected Peer-Reviewed Publications (in chronological order)


Biographical Sketches for each listed Senior/Key Person 6 Page 33
D. Research Support

**Ongoing Research Support**

<table>
<thead>
<tr>
<th>Private Source</th>
<th>2009-2011</th>
</tr>
</thead>
</table>

**A Prospective, Randomized Blinded Multicenter, Parallel Study Comparing Transdermal, Continuous Oxygen Delivery to Moist Wound Therapy (MWT) in the Treatment of Diabetic Foot Wounds**

The goal of this study is to determine if there is a difference in the number of wounds healed within 12 weeks between those receiving transdermal continuous oxygen and those receiving moist wound therapy only.

Role: Study Coordinator

<table>
<thead>
<tr>
<th>Private Source</th>
<th>Grant</th>
<th>2010-2012</th>
</tr>
</thead>
</table>

**Nonvisual Foot Inspection for People with Visual Impairment**

The goal of this pilot study is to determine whether a method of nonvisual foot inspection, using the senses of touch and smell, helps people with diabetes and visual impairment to find new foot problems when they are in early, easily-treated stages.

Role: Data Monitor

<table>
<thead>
<tr>
<th>Private Source</th>
<th>2008-2009</th>
</tr>
</thead>
</table>

**Completed Research Support**

<table>
<thead>
<tr>
<th>Private Source</th>
<th>2008-2009</th>
</tr>
</thead>
</table>

**Evaluation of the Use of the Accu-Cut Osteotomy Guide on the Accuracy, Strength and Stability of an Austin Osteotomy in Cadaver Metatarsals**

The goal of this study was to determine the effect of using an Accu-cut osteotomy guide on the accuracy, strength and stability of an Austin osteotomy in cadaver first metatarsals, and to evaluate the behavior of an Austin osteotomy that was either divergent or convergent in nature.

Role: Co-PI
1. Project Director / Principal Investigator (PD/PI)

<table>
<thead>
<tr>
<th>Prefix</th>
<th></th>
<th></th>
<th>* First Name</th>
<th>Ann</th>
</tr>
</thead>
<tbody>
<tr>
<td>Middle Name</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>* Last Name</td>
<td>Williams</td>
<td></td>
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</tr>
<tr>
<td>Suffix</td>
<td>Ph.D.</td>
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<td></td>
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</tbody>
</table>

2. Human Subjects

- Clinical Trial?  
  - No  
  - Yes

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

3. Applicant Organization Contact

<table>
<thead>
<tr>
<th>Prefix</th>
<th></th>
<th></th>
<th>* First Name</th>
<th>Derek</th>
</tr>
</thead>
<tbody>
<tr>
<td>Middle Name</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>* Last Name</td>
<td>Humphrey</td>
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<tr>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>* Phone Number</th>
<th>216.368.4510</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fax Number</td>
<td>216.368.4679</td>
</tr>
<tr>
<td>Email</td>
<td><a href="mailto:kesada@case.edu">kesada@case.edu</a></td>
</tr>
</tbody>
</table>

- Title: Assistant Director
- Street1: 16960 Euclid Avenue
- Street2:  
- City: Cleveland
- County/Parish:  
- * State: OH: Ohio
- Province:  
- * Country: US: UNITED STATES  
  - Zip / Postal Code: 44106-7015
4. HumanEmbryonic 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://stemcells.nih.gov/research/registry/. 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.
# PHS 398 Modular Budget, Periods 1 and 2

**Budget Period: 1**

Start Date: 07/01/2011  End Date: 06/30/2012

### A. Direct Costs

* Funds Requested ($)  
<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Direct Cost less Consortium F&amp;A</td>
<td>150,000.00</td>
</tr>
<tr>
<td></td>
<td>Consortium F&amp;A</td>
<td>16,314.00</td>
</tr>
<tr>
<td></td>
<td>Total Direct Costs</td>
<td>166,314.00</td>
</tr>
</tbody>
</table>

### B. 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. MTC</td>
<td>57</td>
<td>123,585.00</td>
<td>69,292.00</td>
</tr>
<tr>
<td>2.</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>3.</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>4.</td>
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</tr>
</tbody>
</table>

Cognizant Agency (Agency Name, POC Name and Phone Number)  
DHHS, Denise Shirlpee, 214.747.3313

Indirect Cost Rate Agreement Date: 04/26/2010  
Total Indirect Costs: 69,292.00

### C. Total Direct and Indirect Costs (A + B)

Funds Requested ($) 2,18,125.00

---

**Budget Period: 2**

Start Date: 07/01/2012  End Date: 06/30/2013

### A. Direct Costs

* Funds Requested ($)  
<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Direct Cost less Consortium F&amp;A</td>
<td>125,000.00</td>
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<tr>
<td></td>
<td>Consortium F&amp;A</td>
<td>16,403.00</td>
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<tr>
<td></td>
<td>Total Direct Costs</td>
<td>141,403.00</td>
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</table>

### B. 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. MTC</td>
<td>27</td>
<td>70,323.00</td>
<td>48,084.00</td>
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<tr>
<td>2.</td>
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<tr>
<td>3.</td>
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<td></td>
</tr>
<tr>
<td>4.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Cognizant Agency (Agency Name, POC Name and Phone Number)  
DHHS, Denise Shirlpee, 214.747.3313

Indirect Cost Rate Agreement Date: 04/26/2010  
Total Indirect Costs: 48,084.00

### C. Total Direct and Indirect Costs (A + B)

Funds Requested ($) 181,387.00
# PHS 398 Modular Budget, Periods 3 and 4

## Budget Period: 3

<table>
<thead>
<tr>
<th>Start Date:</th>
<th>End Date:</th>
</tr>
</thead>
</table>

### A. Direct Costs

* Funds Requested ($)

* Direct Cost less Consortium F&A

Consortium F&A

* Total Direct Costs

### B. 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.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

Indirect Cost Rate Agreement Date

Total Indirect Costs

### C. Total Direct and Indirect Costs (A + B)

Funds Requested ($)

## Budget Period: 4

<table>
<thead>
<tr>
<th>Start Date:</th>
<th>End Date:</th>
</tr>
</thead>
</table>

### A. Direct Costs

* Funds Requested ($)

* Direct Cost less Consortium F&A

Consortium F&A

* Total Direct Costs

### B. 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.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.</td>
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<td>4.</td>
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<td></td>
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</tbody>
</table>

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

Indirect Cost Rate Agreement Date

Total Indirect Costs

### C. Total Direct and Indirect Costs (A + B)

Funds Requested ($)
## PHS 398 Modular Budget, Periods 5 and Cumulative

### Budget Period: 5

<table>
<thead>
<tr>
<th>Start Date</th>
<th>End Date</th>
</tr>
</thead>
</table>

#### A. Direct Costs

* Funds Requested ($)

- Direct Cost less Consortium F&A
- Consortium F&A
- * Total Direct Costs

#### B. 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.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.</td>
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<tr>
<td>3.</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>4.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

Indirect Cost Rate Agreement Date

Total Indirect Costs

#### C. Total Direct and Indirect Costs (A + B)

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

---

### Cumulative Budget Information

#### 1. Total Costs, Entire Project Period

- *Section A, Total Direct Cost less Consortium F&A for Entire Project Period*
  - $275,000.00
- *Section A, Total Consortium F&A for Entire Project Period*
  - $32,634.00
- *Section A, Total Direct Costs for Entire Project Period*
  - $307,634.00
- *Section B, Total Indirect Costs for Entire Project Period*
  - $105,276.00
- *Section C, Total Direct and Indirect Costs (A+B) for Entire Project Period*
  - $413,280.00

#### 2. Budget Justifications

- Personnel Justification
- Consortium Justification
- Additional Narrative Justification

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Tracking Number: GRANT16740410

Page 39
Budget Justification

Key Personnel

Ann Williams, PhD, Principal Investigator is a Research Associate, Frances Payne Bolton School of Nursing, Case Western Reserve University (CWRU). She will devote 12 calendar months effort in each year of the study. Dr. Williams is also Co-Investigator of the federally funded FIND Lab (Full INclusion of Persons with Disabilities in Research, P30NR010676-04S1 and 3P30NR010676-04S1). She will oversee fiscal management, direct and coordinate the interdisciplinary research team and project plan that includes recruitment and training of the graduate student assistant, supervision of subject recruitment and data collection, and guidance of data management and data analysis.

Dr. Williams has worked with people who have diabetes and visual impairment in the Greater Cleveland area since 1987, initially as a diabetes educator in blindness rehabilitation settings, and later as a researcher. She has conducted both qualitative and quantitative research focused on the self-management needs of people with diabetes and visual impairment. She has published many articles on diabetes education for people with visual impairment in both professional and lay publications, including journals, magazines, and Internet publications of the American Association of Diabetes Educators, the American Diabetes Association, the American Foundation for the Blind, the International Diabetes Federation, and the National Federation of the Blind. Most recently, she has published the article, “Universal Design in Diabetes Care: An Idea Whose Time Has Come.”

Dr. Williams also has worked within national diabetes and blindness organizations to promote excellence in diabetes care for people with visual impairment. She was a cofounder in 1988 of the Visually Impaired Persons Specialty Practice Group (now the Disabilities Specialty Practice Group) of the American Association of Diabetes Educators (AACE), and chaired this group from 1988 through 1998. She organized, obtained funding for, and chaired a consensus development meeting of an interdisciplinary Task Force on Adaptive Diabetes Education for Visually Impaired Persons, with representation from all major national diabetes and blindness organizations. She also collaborated with others to organize an interdisciplinary consensus conference of representatives from blindness and diabetes organizations on the production of diabetes education materials in low vision format. She was the lead author on several editions of AACE’s Disabilities Position Statement and is the current Chair of AACE’s Disabilities Specialty Practice Group.

Shirley M. Moore, RN, PhD, FAAN, Co-Investigator is Professor and Associate Dean for Research, Frances Payne Bolton School of Nursing, CWRU and will devote 12 calendar months effort each year. Dr. Moore is also Director of the SMART Center and FIND Lab. Dr. Moore has considerable experience building and working in multidisciplinary research teams, including physicians, biomedical engineers, social worker scientists, exercise physiologists, computer scientists, economists and statisticians. She also has extensive experience conducting experimental design intervention studies for cardiac rehabilitation, and has worked with many research participants who have diabetes complications. She will be responsible for providing expert advice about the management of multidisciplinary teams and the conduct of trial-level research on self-management interventions.

David Aron, MD, Co-Investigator is Professor, School of Medicine, CWRU, and Associate Chief of Staff/Education, Louis Stokes Cleveland DVA Medical Center and will devote 12 calendar months effort in each year. Dr. Aron is an endocrinologist with considerable expertise, having provided care for patients with diabetes for over 25 years. He has been involved in research and has had independent funding for over 25 years. He has also been involved in the assessment and improvement of diabetes care delivery. Dr. Aron will provide expert medical advice regarding complicated diabetes management and assist Dr. Williams in the day-to-day troubleshooting of any issues that may arise regarding complex diabetes care or diabetes care delivery.

Nahida Gordon, PhD, Co-Investigator is Professor in the School of Nursing and Professor of Bioethics, School of Medicine at CWRU and will devote 12 calendar months effort to this project. She will be responsible for overseeing the design of the data management and data analysis plans for the proposed study. She will supervise the data analyses and assist with the publication of the results.

Bryan Caldwell, DPM, Co-Investigator is Professor and Dean of Clinical Education at the Ohio College of Podiatric Medicine. He will devote 12 calendar months effort in each year of the study. He will be responsible for
training the Podiatry Students and Residents in the clinic in how to teach nonvisual foot inspection and accurate use of the data collection forms for podiatry visits. He will provide expertise in foot infections and other problems of the diabetic foot. A subcontract will be established with Ohio College of Podiatric Medicine for Dr. Caldwell’s effort to the study. (See Consortium Justification for details).

Jill Carroll, PhD, Data Monitor is Director of Research at the Ohio College of Podiatric Medicine. She will devote 3.9 calendar months effort in each year of the study. She will oversee data collection and monitor for accuracy. She has been in her current position since 1996, has participated in numerous clinical trials, and chairs the OCPM IRB. A subcontract will be established with Ohio College of Podiatric Medicine for Dr. Carroll’s effort to the study. (See Consortium Justification for details).

Other Personnel
Project Coordinator, to be determined (TBD) will devote 3.9 calendar months effort in each year and will be a graduate level nurse with prior research administration experience. The project coordinator will participate in all aspects of the project and will assist in hiring the research staff. She will assist Dr. Williams with the day to day management of the study. She will be responsible for coordinating all aspects of data collection including coordinating and scheduling the intervention sessions (in collaboration with Dr. Williams), data coding, supervision of data entry and cleaning, and assisting in preliminary analyses. She will also be responsible for IRB submissions, annual reports and assuring participant consent was obtained. She will coordinate plans for participant recruitment and monitor the measures for subject retention. She will attend weekly staff meetings, provide day to day personnel management, and supervise the graduate research assistant. Additionally, under the direction of Dr. Williams, the project manager will maintain all records and assist with dissemination of results.

Graduate Research Assistant, TBD, will assist with data collection, data entry, as well as cleaning and analyzing the data for 5 hours per week for 50 weeks in each year of the study at a rate of $15/hr. He or she will assist with the focus groups, making phone calls to subjects every 4 weeks and coordinating the study. He or she will also assist with data analysis.

Podiatry Residents, TBD, will be responsible for conducting the foot exams under the supervision of Drs. Caldwell and Carroll. The Residents will complete the Podiatry Visit Form at each subject visit to the OCPM clinic. The foot exams will be part of their clinical training and will be provided inkind.

Focus Group Facilitator, TBD, will be responsible for leading the focus groups. He or she will have experience in following focus group protocols. $200/focus group * 6 focus groups = $1,200.

Transcriptionist, TBD, will transcribe the recording from each of the focus groups. The service charges $30 per hour for transcription time. Each one hour of focus group time equals three hours of transcription time. Each focus group will last approximately 2 hours. 2 hours * 6 focus groups * 3 hours transcription time * $30/hour = $1,080

CWRU fringe benefit rate is 25% in Year 01, rising 0.5% in year 2. Key Personnel salaries have been raised 2% each year.
CONSORTIUM JUSTIFICATION
Ohio College of Podiatric Medicine (OCPM)

**Estimate of Total Costs**
Year 1: $70,000
Year 2: $71,000

**Personnel**
**Bryan Caldwell, DPM, Co-Investigator** is Professor and Dean of Clinical Education at the Ohio College of Podiatric Medicine. He will devote calendar months effort in each year of the study. He will be responsible for training the Podiatry Students and Residents in the clinic in how to teach nonvisual foot inspection and accurate use of the data collection forms for podiatry visits. He will provide expertise in foot infections and other problems of the diabetic foot.

**Jill Carroll, PhD, Co-Investigator/Data Monitor** is Director of Research at the Ohio College of Podiatric Medicine. She will devote calendar months effort in each year of the study. She will oversee data collection and monitor for accuracy. She has been in her current position since 1996, has participated in numerous clinical studies, and chairs the OCPM IRB.

OCPM fringe benefit rate is 30% in Year 01, rising 0.5% in year 2. Salaries have been raised 2% each year.

Ohio College of Podiatric Medicine is a domestic institution.

Indirect Cost Type: None-currently under negotiation. Proposed Rate -- 30% Salary & Wages
Narrative Justification

Year 1 has an additional module due to start up costs which include recruitment costs, purchasing initial research materials, printer and copy charges for printing instruments and duplication of materials in alternative formats.
# PHS 398 Research Plan

## 1. Application Type:

From SF 424 (R&R) Cover Page. The response provided on that page, regarding the type of application being submitted, is repeated for your reference, as you attach the appropriate sections of the Research Plan.

*Type of Application:

- [ ] New
- [x] Resubmission
- [ ] Renewal
- [ ] Continuation
- [ ] Revision

## 2. Research Plan Attachments:

Please attach applicable sections of the research plan, below.

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<thead>
<tr>
<th>Section</th>
<th>Attachment Name</th>
<th>Additional Information</th>
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<tr>
<td>1. Introduction to Application</td>
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<tr>
<td>2. Specific Aims</td>
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<td>4. Inclusion Enrollment Report</td>
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<td>5. Progress Report Publication List</td>
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### Human Subjects Sections

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<td>7. Inclusion of Women and Minorities</td>
<td>1259-WomenMinorities.pdf</td>
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<td>8. Targeted/Planned Enrollment Table</td>
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<td>9. Inclusion of Children</td>
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### Other Research Plan Sections

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<td>10. Vertebrate Animals</td>
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<td>11. Select Agent Research</td>
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<td>12. Multiple PD/PI Leadership Plan</td>
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<td>15. Resource Sharing Plan(s)</td>
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### Appendix

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NONVISUAL FOOT EXAMINATION FOR PEOPLE WITH DIABETES AND VISUAL IMPAIRMENT

SPECIFIC AIMS

People with diabetes who also have visual impairment have a high risk for foot problems (1), yet foot self-examination is usually taught as a visual procedure. In fact, the recommendation for usual care from both the American Diabetes Association (ADA) and the International Diabetes Federation (IDF) is that visually impaired people seek sighted assistance for daily foot examination.(2, 3) Clinical experience suggests, however, that visually impaired people seldom follow this advice, preferring to use available sighted assistance for other, more urgent needs than foot examination. Consequently, foot self-examination, an essential component of diabetes self-management, may be overlooked or neglected by visually impaired people because it is inaccessible.

There is a need for strategies to address this discrepancy in diabetes care, in order to improve rates of foot examination and early detection of foot problems for this vulnerable population. One potential solution is a simple, novel, low-technology intervention that makes nonvisual foot self-examination available to visually impaired persons. The Multiple Senses and Foot Examination (Multi-SAFE) intervention uses the senses of touch and smell for a systematic, thorough foot self-examination. Fingers are used to detect changes in shape and texture of the feet, ankles, toes, and toenails; the back of the hands or the forearms detect changes in temperature; and the nose detects unusual foot odors that may signal infection. The PI developed the Multi-SAFE intervention and over the past 20 years has taught it to hundreds of patients in clinical practice. Although clinical practice has found that it works, the technique has not been evaluated using research methodology.

The current proposal is for a pilot study of the Multi-SAFE intervention, the technique for nonvisual foot self-examination, a novel self-management technique designed to promote better foot care for people with visual impairment.

Using mixed methods, this pilot study is designed to compare the efficacy, acceptability, and feasibility of the Multi-SAFE intervention with usual care (examination of the visually impaired person's feet by a sighted family member or friend). The study aims are to: (1) compare frequency of foot examination between persons receiving the Multi-SAFE intervention and those receiving usual care, (2) assess the initial efficacy of the Multi-SAFE intervention for detection of new foot problems at home, (3) evaluate the feasibility of the Multi-SAFE intervention compared to usual care in terms of instructional time and classroom resources for teaching the Multi-SAFE intervention, (4) estimate effect size for sample size determination for a future, larger clinical trial, and (5) assess acceptability of Multi-SAFE compared to usual care.

The following Research Questions will be addressed:

1. Are there differences in the frequency of foot examination between participants who receive instruction in the Multi-SAFE intervention compared to those who receive usual care?
2. Do persons who receive the Multi-SAFE intervention detect a greater percentage of new foot problems at home than those who receive usual care?
3. What differences are there in professional instructional time and classroom resources for the Multi-SAFE intervention and usual care?
4. What is the effect size of the Multi-SAFE intervention regarding frequency of foot examination and detection of new foot problems at home?
5. Are there differences in acceptability between the Multi-SAFE intervention and usual care?

Sixty visually impaired adults with diabetes will be recruited through a visual rehabilitation facility and randomly assigned to experimental or comparison groups. Both experimental and comparison groups will receive comprehensive small-group DSME classes in nonvisual format, i.e., with all information (including visual demonstrations and the visual portion of audiovisual materials) communicated audibly and handouts provided in recorded format. The experimental group will be taught Multi-SAFE; the comparison group will be advised to have a sighted person inspect their feet, as recommended by the ADA and IDF. All participants will receive a baseline podiatric evaluation and will be followed for six months at a foot clinic operated by the Ohio College of Podiatric Medicine. A focus group will be conducted at the end of the six months to assess participant's perceptions of the acceptability of the foot inspection methods.

If evidence supports the efficacy of the Multi-SAFE intervention, the potential downstream impact will be increased levels of foot self-examination for the 18% of people with diabetes who have visual impairment, resulting in substantial reductions in foot ulcers, amputations, with greatly increased quality of life. In addition, a significant impact can be expected in the form of decreased overall costs of care for diabetes complications.
RESEARCH STRATEGY

A. Significance:

Foot ulcers and amputations are costly, disabling, and potentially deadly complications of diabetes. Each year in the U.S. an estimated 873,000 people with diabetes are hospitalized with a major foot problem, and 71,000 people with diabetes have a lower extremity amputation. (4) Costs for caring for foot complications of diabetes are estimated at up to $13.7 billion (5), and five-year mortality rates for patients with new ulcers or amputations are reported to range from 43% to 74%. (6)

Foot self-examination for early detection of foot problems is widely recognized as an essential component of comprehensive DSME, and has been an important part of many effective programs designed to prevent foot ulcers and amputations. (7-11) Both the International Working Group on the Diabetic Foot and U.S. Standards for DSME recommend teaching diabetes patients to examine their feet daily as a strategy to promote early detection and treatment of developing foot problems. (3, 12) However, many persons with diabetes do not examine their feet daily. Some recent estimates are as low as 20% to 35% of studied populations reporting daily foot inspection (13, 14), with as many as 55% of some sub-groups reporting never inspecting their feet at all. (15) Nevertheless rates of foot self-examination can be improved. Two recent reviews found that patient education in foot care has a positive influence on patient knowledge and behavior, although the evidence is weak due to methodological shortcomings of the studies. (16, 17) In addition, individualized, targeted foot care education shows promise as a strategy to improve frequency of foot self-examination, especially in high-risk groups. (18-20)

Visual impairment is also common among people with diabetes, with an estimated 3.5 million, or 20% among the 18 million Americans diagnosed with diabetes. (4) Although diabetes self-management education (DSME) is a cornerstone of modern diabetes care, there is little research addressing the DSME needs of people with visual impairment, including foot self-examination. In fact, even though visual impairment is well recognized as a significant risk factor for diabetic foot ulcers and amputations (1, 21), foot self-examination is typically taught visually, with the instruction to “look at your feet every day”. (2, 3) Both the American Diabetes Association (ADA) and the International Diabetes Federation (IDF) recommend as usual care that visually impaired people seek sighted assistance for daily foot examination. (2, 3) The necessity of involving another person for regular foot examination adds a barrier to performance of this activity.

Potential Significance of Findings: Because no special equipment or skills are needed, Multi-SAFE (Multiple Senses and Foot Examination) could readily be incorporated into standard DSME practice throughout the U.S. and worldwide, promoting mainstream accessibility of DSME for the 20% of people with diabetes who have visual impairment. If supported by evidence of efficacy through the proposed and future studies, in the short term, Multi-SAFE will empower individuals with visual impairment to inspect their feet independently and frequently, and seek treatment for minor foot problems while they are still easily treated. Thus it would prevent serious foot problems and greatly increase quality of life for people who otherwise would have experienced foot ulcers and amputations. The potential impact on the population level in the long term is that for every 1% reduction in the necessity to treat diabetic foot complications, Multi-SAFE could reduce costs of care by about $137 million.

B. Innovation

This study challenges current practice by introducing a unique theoretical reframing of foot self-examination to incorporate common but often-overlooked human capabilities: the senses of touch and smell. If foot self-examination is conceived as a multisensory practice, it can be accessible to people who have impairment in one sense and many remaining abilities.

UD is the design of products, environments, and services to be usable by all people, including people with disabilities, without the need for adaptation or specialized design. (22) (See Appendix 1 for the Principles of Universal Design.) Rather than focusing on design for typical individual users, UD focuses on design for typical populations of users, which inevitably include people with varying abilities and disabilities. (22, 23) Originally developed for use in architecture, UD principles have also been applied to education, in the form of Universal Design for Learning (UDL). (24) (See Appendix 2.) Incorporating UDL in a typical group learning situation (such as a class) could mean presenting all necessary information clearly in both visual and auditory modes, so that persons with hearing and visual impairments can perceive all that is presented and learn effectively; and including participatory activities so that persons with either temporary or long-term attention difficulties can more easily engage with the material. Building multiple options for perception and response into the learning design ensures that the learning situation is more effective for learners with a wide range of abilities and disabilities. As an additional benefit, these design features will also enhance learning for typical learners.
The Multi-SAFE intervention is an example of a procedure designed using the principles of Universal Design (UD). It includes multiple options for perception into a common self-management procedure so that persons with visual disabilities can self-manage. Principles #4 of UD and #1 of UDL both state that essential information must be available in more than one sensory mode. Multi-SAFE is built on this principle, using the senses of touch and smell to provide direct sensory information about the feet.

**Preliminary Studies:**

The research team assembled for this project represents a broad spectrum of expertise in research on the DSME needs of people with visual impairment, podiatry, diabetes, and behavior change. The research team consists of Drs. Ann Williams, PhD, RN, CDE (Principal Investigator), Bryan Caldwell, DPM (Podiatrist Investigator), Shirley Moore, PhD, RN, FAAN (behavior change researcher), David Aron, MD (endocrinologist), Nahida Gordon (statistician), and Jill Carroll, PhD (Data Monitor, podiatry researcher), providing an interdisciplinary perspective for this project.

Dr. Williams has conducted research on the self-management needs of people with diabetes and visual impairment. In a focus group study of the accessibility needs of visually impaired people attending DSME programs, she found that major DSME needs for this group included presentation of diabetes self-management skills for visually impaired people (such as nonvisual insulin measurement) in mainstream DSME programs, and presentation of DSME teaching materials, including take-home materials, in accessible formats (i.e., large print and audio recordings). In a participatory action research project, she collaborated with visually impaired people and the Diabetes Association of Greater Cleveland (DAGC) to develop and implement a plan to make DAGC’s DSME programs accessible. Major accessibility changes included: making all DSME teaching materials available in accessible format, planning DSME events for accessibility to public transportation, and development of guidelines to help speakers make their diabetes education presentations accessible for people who cannot see slides and gestures.

Dr. Caldwell has recently completed research on the use of electronic medical records to capture data about the effectiveness of health promotion interventions. He is currently conducting a prospective, randomized blinded multicenter, parallel study comparing transdermal, continuous oxygen delivery to moist wound therapy in the treatment of diabetic foot wounds. His role in those studies was similar to the role he will assume for this proposed study: teaching clinic podiatric residents of the OCPM foot clinic the skills they need to use the study forms and supervising their work in the clinic.

**C. Approach**

The proposed research is a prospective, mixed-methods pilot study. It will use a 2-group randomized clinical trial testing the Multi-SAFE intervention for persons who have both diabetes and visual impairment, and also a focus group for feedback from users about the acceptability of the Multi-SAFE intervention. After receiving the Multi-SAFE intervention, participants will be followed for 6 months.

**Setting:** Both Cleveland Sight Center (CSC) and the Cleveland Foot and Ankle Institute (CFAI) of the OCPM will be sites important to this study. CSC is a comprehensive vision rehabilitation facility serving people who are blind or visually impaired throughout northeast Ohio. CSC will assist with recruiting, provide meeting rooms for classes and focus groups, and assist with coordinating transportation for study participants. CFAI is a state-of-the-art podiatric clinic affiliated with OCPM, providing comprehensive care for foot and ankle problems. CFAI serves as the clinical teaching and outpatient treatment facility for the OCPM, and will provide the podiatric evaluations for this study. These evaluations will be performed by podiatric residents under the supervision of Dr. Caldwell, the Podiatrist Investigator. If participants in the study do not have a source of podiatric care and develop foot problems that require treatment, CFAI will ensure that care is available.

**Target Population and Sample:** The target population is adults who have both diabetes and visual impairment, live in the greater Cleveland area, and either have received or are currently receiving services from CSC. In 2009, CSC served approximately 502 persons with diabetes, of whom approximately 150 were new clients. CSC’s only experience as a recruitment site for research was for small qualitative studies, so no data are available about response to recruitment efforts. However, the pool of potential participants is large enough that 60 persons meeting the study criteria should easily be obtained within a year.

**Sample Size:** The sample size will be 60. Nezizog suggests that a sample size of 20-25 is sufficient for a pilot study in which population effect size is likely to be moderate or greater. (27) Foot ulcers among visually impaired individuals are often the result of negligence due to sensorimotor dysfunction, leading to chronic pain, poor mobility, and impaired self-care.
impaired people with diabetes are reported to range from about 1.4% to 10% annually. (21, 28, 29) No published information is available about the prevalence of precursors of foot ulcers, (such as minor injuries) although a greater prevalence than ulcers seems likely. A sample size of 50 or more would be desirable; allowing for a dropout rate of approximately 20% yields a sample size of 60.

Inclusion criteria: are (a) diagnosis with diabetes (for women, other than during pregnancy); (b) willingness to attend a 3-class diabetes self-management series conducted by staff from the Diabetes Association of Greater Cleveland (DAGC); (c) willingness to receive podiatry care at an Ohio College of Podiatric Medicine (OCPM) Podiatric Clinic for the 6 months of the study; and (d) a score of 65 or below in the 14-item Visual Function Index, the VF-14. The VF-14 is a standardized instrument that measures functional vision, or how well a person functions in vision-related activities of daily living. (30) It can be administered as a pencil-and-paper test or by interview, and has established reliability and validity for many eye conditions. (31) A measure of functional vision, rather than measurements of visual acuity and fields, was chosen for this study because vision in people with diabetes commonly fluctuates, often throughout a single day; a measurement at a particular moment in an eye care provider’s office may or may not reflect the level of visual impairment experienced at other times. A score below 65 on the VF-14 is common among people receiving surgical treatment for a variety of eye diseases, and represents substantial visual impairment in daily life. (32)

Exclusion criteria: are (a) age less than 18 years; (b) inability to pass a 3-item decisional capacity questionnaire about the informed consent form (33); (c) bilateral amputation at the ankle level or higher; (d) inability to put on one’s own socks and shoes, as a proxy for inability to reach the feet with the hands; and (e) inability to feel light touch on two or more fingers. This will be assessed through self-administered testing by the participant, led by the interviewer during the initial telephone screening interview.

Recruitment and Enrollment Procedures: A convenience sample will be recruited through from CSC. Recruitment announcements will be distributed through a newsletter for current and past clients published in accessible formats (large print and audio); low vision support groups throughout the Cleveland area; a radio reading service (broadcast of print materials through a special radio station); and given directly to clients by staff. Announcements will be distributed in a variety of formats: verbally, large print, Braille, in a radio broadcast, and as a recording. Any person expressing interest in participating in the study will be referred to the study team. If needed to increase recruitment, a member of the study team will visit low vision support group meetings and other CSC events to describe the study and answer questions.

Following initial screening by a member of the research team (see Appendix 3), all potential participants will have an opportunity to review an informed consent form in accessible format (large print, Braille, audio recording, or computerized). Persons who sign the informed consent form will either be interviewed by telephone using the Enrollment Form (Appendix 4), or will have the opportunity to fill out the form in accessible format. This form includes questions about demographics, diabetes type and duration, past experiences with DSME, tactile sensitivity, history of foot problems, and vision loss, including the VF-14 (see Inclusion Criteria above for a description). Each of these variables relates to the inclusion criteria (diabetes and visual impairment questions), the intervention (tactile sensitivity and DSME questions), or the outcomes (questions about foot problems). The answers to the questions about diabetes and the VF-14 score will be used to confirm inclusion criteria related to diagnosis with diabetes and visual impairment. In addition, during data analysis all of the variables on the Enrollment Form will be analyzed for co-variance with outcomes.

Randomization: Enrolled participants who meet inclusion/exclusion criteria will be randomly assigned by the minimization method to the experimental or comparison group using a computer containing the minimization stratified randomization program. Minimization is a computerized approach to achieving balance among covariates for treatment assignment within stratification levels. (34) Compared to simple randomization, this technique achieves better balance between intervention and control assignments within levels of stratification variables. (34) Stratification variables will include gender (female, male), race/ethnicity (African American, Caucasian, Hispanic, other), categorical age (18-20 years, 21-50 years, > 50 years), and functional vision level as measured by the VF-14 (< 40, >40).

Intervention: All participants will receive comprehensive DSME that meets national standards, presented by nurse and dietitian certified diabetes educators (CDEs) who are staff from the Diabetes Association of Greater Cleveland (DAGC). All DSME class series will include detailed instruction in foot care as described in national standards. (12) In addition, all participants will be asked to choose one of 3 possible diary systems to keep records of how many days a foot examination is performed: a large print calendar with a thick black marker; a Braille calendar; or a 28-bin pill box and a cup of beans, with instructions to place a bean in the pill box each day that a foot examination is done. Each participant will receive one of these systems, along with coaching in techniques to help them remember to use their
chosen diary system, such as placing the diary in a sock drawer or next to the lotion used on the feet. *Experimental and Comparison Conditions:* The experimental and comparison groups will be instructed in separate cohorts, with approximately 10 individuals from either the experimental or the comparison group in each cohort, for a total of 3 cohorts for each condition, with 3 class sessions delivered to each cohort. The 3 experimental and 3 comparison cohorts will receive different instructions for foot examination, as part of the instruction in foot care that is included in the DSME class series taught by CDEs from DAGC. The experimental group will receive instruction in the Multi-SAFE intervention. This will consist of detailed, in-person instruction concerning how to perform an examination of one's own feet, using the senses of both touch and smell. Participants will be instructed to notice any unusual odors when they remove their shoes and socks; and also to use their fingers to systematically search their toes, toenails, and foot for calluses, blisters, cuts, swelling, areas of roughness, or feelings of soreness; and to use the back of their hands to detect areas of warmth, which may signal inflammation. (See Appendix 5.) *Because Multi-SAFE has not yet undergone rigorous effectiveness testing, participants in the experimental group will also be instructed to have a sighted person look at their feet once a week, and to note the sighted examination in their diaries, using a distinctive written symbol or a different size bean (i.e., a lima bean instead of a navy bean).*

All participants in the experimental group will be asked to perform a return demonstration of the Multi-SAFE foot self-examination procedure, using a set of recorded instructions. Any participant who is unable to perform the procedure correctly will receive extra coaching until he or she can perform all steps in a return demonstration using the recorded instructions. A copy of the recorded instructions will be given to each participant for use at home.

The comparison group will receive usual care instructions to have a sighted person look at their feet regularly for red spots, cuts, swelling, calluses, discolored toenails, cracked skin, blisters, or anything else unusual.

Both groups will receive specific instructions and encouragement to contact the OCPM podiatry clinic for treatment of all foot problems, even those that seem minor.

**Procedures:** Following recruitment, enrollment, and randomization, each participant will be assigned to a class group of 10 people, to receive the DSME classes with either the MultiSAFE intervention or usual care. A DSME class series will begin as soon as possible once 10 participants are assigned to a particular group. Classes will be presented as 3 in-person classes, with one class per week, and will be in accessible format, i.e., all take-home information available in each user's preferred format -- audio recordings, large print, Braille, or computerized -- and all important information from pictures, videos, and demonstrations presented verbally. Classes will be held in a room at CSC, an environment that will be familiar for most of the participants.

To reduce a barrier to participation for the visually impaired participants, who are non-drivers, transportation will be provided to the DSME classes.

*Each participant will receive a baseline podiatric evaluation at the CFAI concurrent with the completion by each cohort of the DSME class series.* For the next 6 months, each participant will receive a phone call every 4 weeks, asking how many days he or she has performed or received a foot examination at home during the last 4 weeks. Each participant will also receive 2 additional comprehensive podiatry evaluation at CFAI, one at 3 months and one at 6 months following completion of the DSME classes. Whenever a participant discovers a foot problem at home and calls CFAI, an additional evaluation will be scheduled and care provided for the foot problem.

Within 2 weeks of completion of 6 months in the study, each DSME class group will participate in a focus group, to be held at CSC, to discuss their impressions of using the method of foot examination they were taught.

*Fidelity of the Intervention and Contamination:* To promote standard delivery of the intervention, a written procedure for the Multi-SAFE intervention has been designed for the CDEs who will deliver it. They will be trained using an intervention manual and role-playing demonstrations. Adherence to the intervention protocols by the CDEs will be monitored using an intervention checklist for each class, review meetings with a research team member between class series, and episodic monitoring of the intervention sessions. Receipt of the intervention by participants will be monitored by tracking attendance sheets for the DSME classes and by checklists ensuring that the recorded instruction materials were given to each participant. To reduce the likelihood of contamination across study groups, both experimental and comparison groups will be given specific instructions not to share materials or ideas discussed in the class sessions with individuals who were not in their group. Appeals will be made to them to keep the information confidential, since this is a research study.
Variables and Data Collection:

**Foot examination at home:** The primary outcome variable is the frequency of foot examination at home, defined as the number of days per week that a participant performs the method of foot examination that he or she was taught. Performance of foot examination will be tracked through one of the diary systems described above. Every 4 weeks, all participants will receive a phone call asking them to report how many days a foot examination was done, and coaching them on remembering to use their diary systems.

**Percent of new foot problems discovered at home:** The second outcome variable is the percent of total new foot problems that were discovered at home. This variable will be tracked using the Podiatry Visit Form (Appendix 6), to be filled out for each participant by the examining podiatric resident at each visit to an OCPCM clinic. Each participant will be seen for a baseline comprehensive podiatry examination within 3 weeks of completion of the DSME classes. Repeat comprehensive podiatry examinations will be conducted at 3 and 6 months following the initial foot exam, with additional podiatry visits if new foot problems are discovered at home. Transportation will be provided to podiatry appointments.

The Podiatry Visit Form was designed for this study by the Project Podiatrist. It includes: questions for documentation of any problems found at home, a list of common minor foot problems that are potential precursors to foot ulcers, the PEDIS (Perfusion, Extent, Depth, Infection, Sensation) classification system for foot wounds, as developed by the International Working Group on the Diabetic Foot, and space for documenting any other foot problems. PEDIS was designed for use in research, and has been validated in a longitudinal study. To ensure accurate data collection, the Project Podiatrist will teach the clinic podiatric residents the skills for using this form and the Director of Research from OCPCM will serve as data monitor.

For this study, “percent of total foot problems discovered at home” will be calculated for the experimental and comparison groups using “number of foot problems discovered at home” and “number of total new foot problems.” “Number of foot problems discovered at home” is defined as the number of foot problems that a participant or sighted assistant discovers at home and is confirmed by a podiatrist in the OCPCM clinic. “Number of total new foot problems” are defined as the total number of foot problems newly documented at any OCPCM podiatry examination after the baseline examination. Brief descriptive lists of the types of foot problems found at home and by podiatrists in each condition, including stage of any ulcers discovered, will be compiled to make this count.

**Instructional time and classroom resources:** A third set of variables concerns the professional instructional time and classroom resources for teaching both the Multi-SAFE intervention and usual care. A very simple comparative analysis is planned for these variables. Contact time between the participants and the CDEs devoted to teaching foot examination, types and costs of handouts, and types and costs of any other supplies used for teaching foot examination will be recorded for both the Multi-SAFE intervention and usual care, totaled for all experimental and control groups, and divided by the number of participants in those groups.

**Acceptability:** Acceptability of the Multi-SAFE Intervention and usual care will be assessed using qualitative data from focus groups. Focus groups were chosen because they offer the opportunity to efficiently elicit data about the subjective experiences of a relatively large number of persons, in this case, all enrolled participants in this pilot study. In addition, rather than attempting to fit participants' thoughts and feelings into categories shaped by the researcher's ideas, this approach will explicitly encourage the visually impaired participants to express their own views in their own words.

After each of the 6 cohorts has completed 6 months in the study, an independent facilitator will conduct a focus group with that group of participants, with transportation provided. The focus groups will be held in a room at CSC, an environment likely to feel familiar and comfortable to this group of CSC clients. Two hours will be allowed for each focus group discussion. An interview guide will be used to guide the discussion. (See Appendix 7.) Participants will initially be asked to think back to the time they were in class together and learned how to care for their feet, and asked open-ended questions designed to stimulate discussion of their experiences and feelings concerning their initial impressions of the method of foot inspection they were taught. The discussion will then move to their experiences with the foot examination technique and their feelings about it. Each focus group will be audio-recorded, and the facilitator will be asked to keep notes about nonverbal expressions, such as body language and other indicators of group mood. The PI and the Podiatrist Investigator will observe the groups without speaking to or interacting with participants, to keep their own records of nonverbal expressions.

**Data Analysis and Interpretation:**

Two types of analyses are contemplated for the study question outcomes. The first will be a preliminary analysis using exploratory data techniques to examine univariate characteristics (central tendency, dispersion, and distribution) and bivariate relationships (correlations) among covariates and covariates with outcomes. For
continuous variables, which do not have a linear relationship with the outcome, appropriate transformations or
categorization will be considered. For nominal and ordinal variables, the number and type of categories will be
considered to obtain the optimum relationship, if any, with the outcome. A multivariate regression analysis will be
implemented for outcomes measured on the interval scale. An indicator variable representing treatment type
(intervention vs. control) will be created. Once a preliminary model containing significant main factors, interaction
terms between the treatment indicator variable and other the main factors will be considered. Estimates of
regression coefficients and their variance-covariance matrix will serve as the basis for testing the hypotheses.

For Research Question 1, “Are there differences in the frequency of foot examination between
participants who receive instruction in the Multi-SAFE intervention compared to those who receive usual care,”
the bivariate relationship between the Multi-SAFE intervention and frequency of examination will be estimated
using Fisher’s Exact test as well as a multivariate linear regression of the frequency of examination upon
covariates and the Intervention Indicator variable. The procedure for this analysis is outlined above.

For Research Question 2, “Do persons who receive the Multi-SAFE intervention detect a greater
percentage of new foot problems at home than those who receive usual care,” a similar analysis is planned. A
brief description of all new foot problems, including stage of any ulcers discovered in the study, will be
included with the analysis for this question.

For Research Question 3, “What differences are there in professional instructional time and classroom
resources for the Multi-SAFE intervention and usual care,” for each of the 3 experimental group cohorts,
the total time used to provide instruction in foot examination and the total cost of classroom resources used will
be calculated and compared to the total time and resources for each of the 3 comparison group cohorts.

For Research Question 4, “What is the effect size of the Multi-SAFE intervention regarding frequency of
foot examination and detection of new foot problems at home,” effect sizes for these outcomes will be
determined from the means and variances obtained for each of the levels of the intervention indicator variable.
Given a sample size of 60, type I error of 0.05, power of 0.95, the addition of one covariate to a model that
already contains 10 covariates will detect an increase of $R^2$ of 0.29 or an effect size of .225. Effect size is
defined as $R^2/(1+R^2)$. (35)

For Research Question 5, comparing the acceptability of Multi-SAFE and usual care, the focus group
data will be transcribed verbatim by an independent transcriptionist using the recordings. Data will be analyzed
using Atlas.ti software. Atlas.ti is software for qualitative analysis of textual, graphical, audio and video data.
Data analysis will be conducted by Dr. Williams, who has experience with qualitative techniques. Drs. Caldwell
and Moore will also participate in data interpretation, offering their perspectives as a podiatrist and a nurse
designing health behavior change interventions. Using a grounded theory approach, a line-by-line analysis
of each focus group discussion will be conducted, and emerging themes related to acceptability of Multi-SAFE
and usual care will be identified. Key words and significant statements will be identified, keeping them in the
words of the participants. A summary of themes will be developed from each focus group and compared with
subsequent focus groups for similarities and differences. Analysis will continue until no new themes emerge. A
detailed summary of the themes associated with acceptability of each method of foot examination will be
produced. An auditable trail will be documented through which other researchers will be able to follow the
identification of themes from the raw data to the final descriptions.

Time Line: The study is planned for completion in 24 months. Each of the 6 DSME class groups will
be scheduled to begin sequentially as it is filled, approximately 1-2 months apart. Following is an estimated
time line. Mo 1-4: hire project personnel; finalize protocols and IRB approvals; train DAGC CDEs and podiatry
residents; begin recruiting participants; Mo 4-8: complete enrollment for first 20 participants; conduct DSME
classes and baseline podiatry evaluations; begin data collection: telephone calls and follow-up podiatry
evaluations; Mo 9-20: continue enrolling participants and conducting DSME classes and baseline podiatry
evaluations as new groups are filled; complete final telephone calls and podiatry evaluations when due;
conduct focus groups for each class group when due; Mo 21-24: complete final data collection: phone calls,
podiatry evaluations, and focus groups; data cleaning and analysis.

Potential Challenges: Retention of participants in the study may be a problem, and will be addressed
by offering cash incentives: $50 for completion of all 3 DSME class series, $20 for each of 3 podiatric
evaluations, and $20 for attendance at the focus group. Convenience sampling limits generalizability of the
results of this study, since those who volunteer for the study may not be representative of the study population.
However, for a pilot study it has the advantage of limiting time, cost, and effort for sampling. Aggregate
demographic information of those who participate in the study will be compared to that of CSC clients with
diabetes served in the last year to determine similarities and differences.
Human Subjects

Human Subjects Involvement and Characteristics

The proposed study will involve the participation of 60 persons with both diabetes and visual impairment. Exclusion criteria include inability to pass a 3-item questionnaire about the informed consent form, as a test of decisional capacity.

Human Subjects' Approval and Authorization for collection of Protected Health Information (PHI) will be obtained from Case Western Reserve University and the Ohio College of Podiatric Medicine. Participants will hear about the study through Cleveland Sight Center. A variety of methods of publicizing the study are planned: through a newsletter for current and past clients published in accessible formats (large print and audio); low vision support groups throughout the Cleveland area; a radio reading service (broadcast of print materials through a special radio station); and verbally from staff. Announcements containing study information will be distributed in a variety of formats: verbally, large print, Braille, in a radio broadcast, and as a recording. Any person expressing interest in participating in the study will be referred to the study team. If needed to increase recruitment, a member of the study team will visit low vision support group meetings and other CSC events to describe the study and answer questions.

All participants will be given a short verbal explanation of the study that describes the study purposes, the extent of their involvement, confidentiality of information, benefits and risks, and right to withdraw from the study. Consent forms will be provided to each participant in the format preferred by that person: large print, audio recording, Braille, or electronic format. All participants will sign a printed consent form to participate, and will immediately receive a copy of what they signed so they can ask a trusted person to confirm what they signed. Persons who sign the informed consent form will either be interviewed by telephone using the Enrollment Form (Appendix 4), or will have the opportunity to fill out the form in accessible format. This form includes questions about demographics, diabetes type and duration, past experiences with DSME, tactile sensitivity, history of foot problems, and vision loss, including the VF-14, a measure of functional vision. Those individuals who meet study requirements will then be enrolled in the study and randomized to the experimental or comparison group.

All participants will be offered at a 3-class series of Diabetes Self-Management Education (DSME) that meets national standards, taught by a nurse and a dietitian who are both CDEs and staff members of the Diabetes Association of Greater Cleveland (DAGC). The DSME classes have been adapted to facilitate the involvement and participation of the visually impaired by offering direct teaching and take-home materials in a way that accommodates visual disabilities and personal preferences (e.g., materials offered in a variety of formats: large print, audio, Braille, and electronic). The participants will either be taught a nonvisual method of examining their own feet (experimental group) or to ask a sighted person to inspect their feet (comparison group). They will also be given a tactile method of keeping track of how often they examine their feet: a 28-day pill box and a container of beans with instructions to put a bean in the box each time they or someone else examines their feet. Within 3 weeks of completion of the classes, all participants will be scheduled for comprehensive baseline podiatry examinations at the Cleveland Foot and Ankle Institute (CFAI), a podiatry clinic operated by the Ohio College of Podiatric Medicine (OCPM). Each participant will be followed for 6 months. During that time, they will all receive a phone call every 4 weeks to ask how often they or someone else examined their feet. In addition, all participants will have 2 more comprehensive podiatric examinations, one each at 3 and 6 months. Additional podiatric examinations will be scheduled if a participant discovers a new foot problem at home and contacts CFAI for follow-up. As part of the study protocol, participants are instructed to contact CFAI when they notice any foot problems, even minor problems. After the 6 months in the study, participants will attend a focus group to discuss their impressions of using the method of foot examination they were taught. Transportation to all study activities will be provided for all participants, who are not drivers, in order to remove a potential barrier and reduce undue burden for participation.

Potential Risks

Risks to all participants as a result of the study activities are minimal. It is possible that some participants may experience some anxiety during the DSME classes, especially when covering material relating to complications they may have. The CDEs who teach these classes are experienced diabetes education professionals, accustomed to helping minimize anxiety to maximize learning. In addition, loss of confidentiality is always a risk of participation in a study. This risk will be minimized as outlined below.
Confidentiality
Every effort will be made to keep the study data confidential. All responses of participants will remain confidential and results will be reported in aggregate form. Data collection forms will be computerized and identified only by a study-specific identification number. No names will appear on the study data collection forms. An index of subjects' names, OCPM medical record numbers, and study-specific identification numbers will be kept in locked project files during the data collection phase. Data will be stored and backed up in a computerized system designed for secure data storage for researchers. Only personnel directly related to the project will have access to the data. At the completion of data collection and verification of data integrity, the list linking the subject name and medical record number with corresponding study-specific identification number will be destroyed.

Potential Benefits of the Proposed Research to the Subjects and Others
A possible benefit to participants in this study is an increase in knowledge about ways to manage diabetes, especially regarding foot health, through attendance at the DSME classes. Participants may develop a habit of regular foot self-examination. Furthermore, any participants who have not had regular podiatric care previously will have the benefits of regular podiatric care during the study, which is recommended for all people with diabetes and visual impairment. The risks of this study are reasonable in relation to the potential benefits in this population.

Importance of the Knowledge to be Gained
This study will provide initial evidence about the effectiveness of MULTI-SAFE to increase frequency of foot examination in visually impaired diabetic patients. An estimated 3.3 million people in the U.S. have diabetes and visual impairment. Visual impairment is a risk factor for foot ulcers and amputations among people with diabetes. Foot ulcers and amputations are costly, disabling, and potentially deadly complications of diabetes. They are both a source of pain and suffering for the individuals who experience them, and also a source of a major preventable health care expense.

Data Safety and Monitoring
A Data Safety and Monitoring Committee (DSCM) will be set up with three investigators who are not involved in the study. The three investigators will be researchers with expertise in RCTs, biostatistics and/or outcomes studies, consistent with the scope of the present study. The DSMC will meet after the first 20 subjects are recruited, enrolled and randomized and at least quarterly once all 60 participants are enrolled. At each meeting, the DSMC will review: study-specific adverse events; data quality, completeness and timeliness; adequacy of enrollment (including enrollment of women and minorities according to the enrollment plan); adherence to the protocol; and study results to date. The study results will be compared by group (intervention vs usual care) to ascertain whether there are concerns about participant safety or serious enrollment concerns. If needed, the DSMC has access to other CWRU resources (i.e., CWRU CTSA; CWRU IRB) in the event that additional outside consultation is required. The DSMC will make recommendations to the PI and investigative team regarding their findings and recommendations. The PI will follow NIH reporting requirements for adverse events and reporting.
Inclusion of Women and Minorities
It is expected that 60% of the participants in the study will be women. According to the 2008 U.S. census figures, in Cuyahoga County, where this study will be held, the population is 52.6% female and 47.4% male. For many years, CSC has served a population that is approximately 60% female and 40% male.

48% of study participants will be minorities. It is expected that 45% of the participants will be African American and 4% Latino. In 2008 in Cuyahoga County, the population was 29.3% African American, 66.8% Caucasian, 2.3% Asian, and a total of 4.4% ethnically Latino (all races). Other races totaled less than 1%. In 2008, CSC served a total of 502 people with diabetes. Among these, 45% were African American, 52% were Caucasian, 1% were Asian, and a total of 2% Latino (all races).
Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: Nonvisual Foot Examination For People With Diabetes And Visual Impairment

Total Planned Enrollment: 60

| TARGETED/PLANNED ENROLLMENT: Number of Subjects |
|-----------------------------------------------|-----------------------------------------------|
| Ethnic Category                  | Sex/Gender                                   |
|                                 | Females | Males | Total |
| Hispanic or Latino               | 2       | 1     | 3     |
| Not Hispanic or Latino           | 37      | 20    | 57    |
| Ethnic Category: Total of All Subjects * | 39     | 21    | 60    |

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<td>American Indian/Alaska Native</td>
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<td>Asian</td>
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<tr>
<td>Native Hawaiian or Other Pacific Islander</td>
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<tr>
<td>Black or African American</td>
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<tr>
<td>White</td>
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<tr>
<td>Racial Categories: Total of All Subjects *</td>
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</tbody>
</table>

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."
Inclusion of Children
Children very rarely develop visual impairment with diabetes. However, it is possible. Anyone over the age of 18 who otherwise meets the study criteria will be included in this study. Children under the age of 18 will not be included, both because it is very unlikely that we will find one of this age group who meets the study criteria, and also because at younger ages children and parents share responsibility for diabetes management at varying levels.
References


Title of your project: Nonvisual Foot Examination for People with Diabetes and Visual Impairment

Bryan Caldwell, Professor and Dean of Clinical Education
Jill Carroll, Director of Research
Ohio College of Podiatric Medicine (OCPM)

Programmatic
Bryan Caldwell, DPM, Co-Investigator is Professor and Dean of Clinical Education at the Ohio College of Podiatric Medicine. He will devote ______ calendar months effort in each year of the study. He will be responsible for training the Podiatry Students and Residents in the clinic in how to teach nonvisual foot inspection and accurate use of the data collection forms for podiatry visits. He will provide expertise in foot infections and other problems of the diabetic foot.

Jill Carroll, PhD, Co-Investigator/Data Monitor is Director of Research at the Ohio College of Podiatric Medicine. She will devote ______ calendar months effort in each year of the study. She will oversee data collection and monitor for accuracy. She has been in her current position since 1996, has participated in numerous clinical studies, and chairs the OCPM IRB.

Fiscal and Administrative
A subaccount will be set up where Dr. Caldwell will be paid ______ calendar months effort in each year, and Dr. Carroll will be paid ______ calendar months effort in each year. Funds for travel to a conference will be budgeted in each year for Dr. Caldwell. OCPM is in the process of negotiating an indirect rate – currently proposed at 30% salary and wages.

The appropriate programmatic and administrative personnel of each institution involved in this grant application will establish written inter-institutional agreements that will ensure compliance with all pertinent Federal regulations and policies in accordance with the “NIH Grants Policy Statement,” PHS 398 “Application for Public Health Service Grant,” and the NIH “Guidelines for Establishing and Operating Consortium Grants.”
Letters of Support

Helen M. Dumski, MA, RD, LD, President & CEO, Diabetes Association of Greater Cleveland

Vincent J. Hetherington, DPM, Vice President and Dean of Academic Affairs, Ohio College of Podiatric Medicine

Peggy Kealing, MA, MSW, LISW-S, Director, Senior & Outreach Services, Cleveland Sight Center
November 7, 2010

Ann Williams, PhD, RN, CDE
Frances Payne Bolton School of Nursing
Case Western Reserve University
10900 Euclid Avenue
Cleveland, OH 44106-4904

Dear Dr. Williams:

I am pleased to submit this letter of support for your research project, "Nonvisual Foot Examination for People with Diabetes and Visual Impairment" that you are submitting for a National Institutes of Health R21 grant. I understand this pilot study will focus on the Multi-SAFE intervention, a method of nonvisual foot examination for people with diabetes and visual impairment using the sense of touch and smell. It will compare the efficacy, acceptability, and feasibility of the Multi-SAFE intervention with usual care (advice to have a sighted person examine the feet) by: comparing the frequency of foot examination between persons receiving the Multi-SAFE intervention and those receiving usual care; assessing the acceptability of Multi-SAFE compared to usual care; assessing the initial efficacy of the Multi-SAFE intervention for detection of minor foot problems; evaluating the feasibility of the Multi-SAFE intervention compared to usual care in terms of instructional time, classroom resources, and costs for teaching the Multi-SAFE intervention; and estimating effect size for sample size determination for a future, larger clinical trial.

The Diabetes Association of Greater Cleveland (DAGC), founded in 1954, is Northeast Ohio's only local and independent diabetes-focused organization and is not affiliated with any national diabetes organization (such as the American Diabetes Association or the Juvenile Diabetes Research Foundation). Its mission is to improve the lives of people with diabetes by leading the Northeast Ohio community in its prevention, management, and cure. Our diabetes educators serve more than 9,000 people annually through community-wide diabetes education, diabetes self-management education, medical nutrition therapy, risk assessments, emergency diabetes supplies, telephone and online help, and much more. In addition, DAGC owns and operates Camp Ho Mita Koda for children with diabetes in Newbury (Geauga County) and is a large supporter of local diabetes research through its Dietrich Diabetes Research Institute.

DAGC will collaborate with you on the research project by providing comprehensive Diabetes Self-Management Education (DSME) for all participants. The DSME will be provided in small groups, and will include detailed instruction in nonvisual foot inspection for the experimental group and usual care for the comparison group. It will also include recorded handouts for all participants in place of the printed handouts usually provided to sighted participants. Thank you for inviting us to collaborate with you in this research project. We look forward to working with you on this important and worthwhile project.

Sincerely,

Helen M. Dumski, MA, RD, LD
President & CEO
Ann Williams, PhD, RN, CDE
Frances Payne Bolton School of Nursing
Case Western Reserve University
10900 Euclid Avenue
Cleveland, OH 44106

October 27, 2010

Dear Dr. Williams:

I am pleased to supply this letter of support for your research project, entitled "Nonvisual Foot Examination for People with Diabetes and Visual Impairment". I understand that this pilot study will focus on the Multi-SAFE intervention, a method of nonvisual foot inspection for people with diabetes and visual impairment using the senses of touch and smell. It will compare the efficacy, acceptability, and feasibility of the Multi-SAFE intervention with usual care (advice to have a sighted person examine the feet) by; comparing the frequency of foot examination between persons receiving the Multi-SAFE intervention and those receiving usual care; assessing the acceptability of Multi-SAFE compared to usual care; assessing the initial efficacy of the Multi-SAFE intervention for detection of minor foot problems; evaluating the feasibility of the Multi-SAFE intervention compared to usual care in terms of instructional time, classroom resources, and costs for teaching the Multi-SAFE intervention; and estimating effect size for sample size determination for a future, larger clinical trial.

The Ohio College of Podiatric Medicine (OCPM) is one of eight colleges of podiatric medicine in the country. Podiatric medicine is a refined field of medicine, with podiatric physicians possessing expertise in the normal and pathological foot and ankle. In keeping with our vision to be the premier college of podiatric medicine and to produce highly competent doctors of podiatric medicine, research is emphasized at OCPM, as research is the primary means by which significant advances are made in the field.

OCPM will collaborate with you on the research project in the following ways:

- OCPM will provide foot examinations and foot care for study participants through an OCPM-affiliated foot clinic (Cleveland Foot and Ankle Institute).
- Bryan Caldwell, DPM, of the OCPM faculty will serve as the Project Podiatrist.
- Jill Carroll, PhD, will serve as Study Monitor for the foot evaluations.

Thank you for inviting us to collaborate with you in this research project. We look forward to working with you on this important and worthwhile project.

Sincerely,

[Signature]

Vincent J. Hetherington, DPM
Vice President and Dean of Academic Affairs
October 25, 2010

Ann Williams, PhD, RN, CDE
Frances Payne Bolton School of Nursing
Case Western Reserve University
10900 Euclid Avenue
Cleveland, OH 44106-4904

Dear Dr. Williams:

I am pleased to supply this letter of support for your research project, "Nonvisual Foot Inspection for People with Diabetes and Visual Impairment" that you are submitting for a National Institutes of Health R21 grant. I understand this pilot study will focus on the Multi-SAFE intervention, a method of nonvisual foot inspection for people with diabetes and visual impairment using the sense of touch and smell. It will compare the efficacy, acceptability, and feasibility of the Multi-SAFE intervention with usual care (advice to have a sighted person examine the feet) by: comparing the frequency of foot examination between persons receiving the Multi-SAFE intervention and those receiving usual care; assessing the acceptability of MultiSAFE compared to usual care; assessing the initial efficacy of the Multi-SAFE intervention for detection of minor foot problems; evaluating the feasibility of the Multi-SAFE intervention compared to usual care in terms of instructional time, classroom resources, and costs for teaching the Multi-SAFE intervention; and estimating effect size for sample size determination for a future, larger clinical trial.

Cleveland Sight Center (CSC), founded in 1906 as The Cleveland Society for the Blind exists to create opportunities for persons with impaired vision to lead rich lives, full of achievement. With a mission, "to empower people with visual impairment to realize their full potential, and to
CSC will collaborate with you on the research project in the following ways:

- CSC will help recruit participants for the study by publicizing it to our clients through a variety of methods: our newsletter sent in accessible formats, information given to support groups throughout the Cleveland area, our radio reading service, and information given to clients directly by our staff.
- CSC will provide meeting space for the diabetes self-management education classes and for focus groups.
- The CSC transportation department will provide or arrange transportation for study participants to all study activities.

Thank you for inviting us to collaborate with you in this research project. We look forward to working with you on this important and worthwhile project.

Sincerely,

Peggy Keating, MA, MSW, LISW-S
Director, Senior & Outreach Services
1. Application Type:
   From SF 424 (R&R) Cover Page. The responses provided on the R&R cover page are repeated here for your reference, as you answer the questions that are specific to the PHS398.

   * Type of Application:
     - [ ] New
     - [x] Resubmission
     - [ ] Renewal
     - [ ] Continuation
     - [ ] Revision

   Federal Identifier: [REPLACE WITH ACTUAL FEDERAL IDENTIFIER]

2. 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:

3. Inventions and Patents  (For renewal applications only)

   * Inventions and Patents:  Yes [ ]  No [x]

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

   * Previously Reported:  Yes [ ]  No [ ]
4. * Program Income

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

- [ ] Yes
- [x] 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. * Disclosure 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)?

- [x] Yes
- [ ] No