



Diabetes Research Center

UNIVERSITY of WASHINGTON

PILOT AND FEASIBILITY AWARD

General Application Instructions

The application is an abbreviated version of the standard NIH application. Please abide by the page limitations. The application will be reviewed as a pilot proposal and need not be as detailed as a full R01 grant application.

The application must be a PDF file and formatted using either Helvetica or Arial fonts no smaller than 11 point and margins must be no smaller than 0.5 inches. Applications that do not conform to these requirements will not be reviewed.

Please note: DRC uses the "Just-in-Time" method for all approvals. IRB and IACUC approvals are not required at the time of application submission. Before any funding can be distributed, verification must be provided to the DRC as follows:

- If the proposed research involves human subjects, IRB approval memo is required before funds will be released. Note: The DRC is NIH funded, award number P30 DK017047.
- If the research involves vertebrate animals, please provide IACUC approval signature and protocol information on the application cover page.

The Department Chair or Division Head's signature must be obtained before the application can be considered complete. Electronic signatures are acceptable.

This is an internal application. As such, DO NOT complete the eGC-1 process or send the application to the UW Office of Sponsored Programs.

You must submit a budget for up to two years, for a maximum of \$50,000 annually.

The application deadline is February 24, 2020, with awards beginning July 1, 2020. If you have any questions, please contact the DRC Program Operations Specialist (Celia Chor; 206-764-2695), DRC Manager (Corinne Lovato; 206-764-2692), Director of P&F Programs (Dr. Sakeneh Zraika; 206-768-5391) or Associate Director of P&F Programs (Dr. Mario Kratz; 206-667-7362).

NOTE: If you wish to use the Diabetes Research Center's core services, information that describes the Center, its cores and the charges for core services can be found at:

<http://depts.washington.edu/diabetes>

Detailed Application Instructions

Cover Page. Provide the information requested, including human subject and animal care committee review and approval information. If approvals are pending, indicate "pending" in the space provided.

Please note: DRC uses the "Just-in-Time" method for approvals. List the key collaborators engaged in the project. Principal Investigator and Department Chair or Division Head signatures are required at the time of submission for applications to be considered complete. Electronic signatures are acceptable.

Project Summary/Abstract. For the abstract, summarize the scientific aims, rationale and approach for achieving the stated goals (limited to 30 lines of text). In the space provided, indicate DRC core facilities that will be used. Information that describes the DRC core facilities, and charges for core services can be found at <http://depts.washington.edu/diabetes>

Budget for the first 12 months. List the direct costs requested under the major categories listed. The maximum request cannot exceed \$50,000 per year. Requests for travel and equipment funds are not usually successful, thus they must be carefully justified. Subcontracts are permitted however they are discouraged as set-up and implementation can be a lengthy process and any associated indirect costs will be subtracted from the \$50,000/year in direct costs.

Personnel. List the names and positions of all personnel involved in the project, whether or not salaries are requested in the application. For each person indicate the base salary, calendar months to be devoted to this project, and the salary amount requested. Describe the contributions of each person to the project in the budget justification section. Salary support for postdoctoral fellows and/or graduate students is not allowed.

Equipment. Application for equipment purchase of items over \$500 is discouraged. If such items are requested, they must be extensively justified.

Supplies. Itemize supplies such as glassware and plasticware, chemicals, radioisotopes, and animals in separate categories. Justify these items. If animals are involved, state how many are to be used and their unit purchase cost. Indicate their unit care cost in the "Other Expenses" category.

Patient Care Costs. Indicate in detail the basis for estimating costs in this category, including the number of patient days; estimate cost per day and cost per test or treatment.

Alterations and Renovations. **Not allowed.**

Tuition. **Not Allowed.**

Travel. Provide the purpose and destination of each trip and the number of individuals for whom funds are requested. Note, the purpose of travel must be closely related to your project. Explain in the Budget Justification section.

Other Expenses. Itemize other expenses, such as publication costs, computer charges, equipment maintenance agreements, animal care costs, research subject reimbursement, etc. by category and unit costs. Justify all items.

Use of DRC Core Facilities. Describe the proposed use of core laboratory services indicating the number of tests or other service units required from each core laboratory. Indicate whether the use of the core(s) has been discussed with the Core Director. Information on the cores is located at <http://depts.washington.edu/diabetes>

Budget for the Entire Proposed Period, Budget Justification. Self-explanatory.

Biographical Sketch. Provide a separate biographical sketch for yourself, your collaborators and each professional engaged in the project, using the standard NIH format described at <https://grants.nih.gov/grants/forms/biosketch.htm>. Detailed instructions and a sample are provided in Appendix A of this document.

Other Support. List all active and pending grant support for yourself, your collaborators and each professional engaged in the project. An example is provided in Appendix B of this document. Provide abstracts for all active support for yourself and key collaborators listed on the cover page. Describe the relationship of any pending applications to this proposal.

Resources and Environment. Briefly describe the resources available to you to conduct and support the proposed research, including laboratories, clinical resources, office space, animal facilities, equipment, etc.

Research Plan. The page limitations for each section are suggested guidelines, but the research plan must not be longer than **6 pages (the 6-page limitation applies to parts A-E)**. In Section A, explain your eligibility. In sections B-E, describe what you intend to do. Why is the research important? What has already been done by you or others? How are you going to do the research?

- A. Eligibility.** In a brief paragraph, explain (a) why you consider yourself to be eligible for a DRC Pilot and Feasibility award and (b) how the award will benefit your career development as an independent investigator in the field of diabetes research. Note that these research awards are primarily intended to be first grants for new/junior faculty who have not yet obtained a major peer-reviewed grant (e.g., NIH). Senior faculty are eligible if their projects represent a first entry into the field of diabetes research. If you do not hold a University of Washington faculty position at the time that you submit the application, include a letter from your department head or division chair to verify your pending faculty appointment.
- B. Specific Aims.** Outline the major question(s) to be investigated.
- C. Significance.** Describe the importance of the research in the context of the present status of the problem. Describe the scientific premise for the proposed project, including consideration of the strengths and weaknesses of published research or preliminary data crucial to the support of your application.

Eligibility, Specific Aims and Significance together are recommended **to be two pages**.

- D. Preliminary Studies and Specific Background Information.** In this section, include personal experience and preliminary data that highlight the applicant's expertise to perform the proposed research. Data to support the feasibility of the proposed experiments is highly encouraged. Pertinent background from the literature for the proposal should also be included. **One page** is recommended.

E. Experimental Design and Methods. Briefly present the experimental plan for addressing the specific aims. Describe the protocols and methods to be used, including details relating to scientific rigor and unbiased study design. Explain any new methods to be developed and indicate why you have chosen a new approach. Discuss how the data will be analyzed (statistics). Describe the expected outcomes. Discuss potential difficulties/limitations, and alternatives that may be used to circumvent them. Explain how relevant biological variables (e.g. sex) are factored into the study design and analyses. This section need not cover every experimental detail. It should convey your understanding of the important considerations and problems inherent in your proposed experimental approach. **Three pages** is recommended.

F. Human Subjects. All applicants must complete Section A. Complete Section B if applicable.

NOTE: DRC uses the “Just-In-Time” method for required approvals. Therefore, before funding can be distributed, the IRB protocol must be approved and approval memo provided to the DRC.

G. Vertebrate Animals. If the research involves vertebrate animals, address the following points.

1. Provide a detailed description of the proposed use of animals. Identify the species, strains, ages, sex, and numbers of animals to be used in the proposed research.
2. Justify the use of animals, the choice of species, and the numbers used. If animals are in short supply, costly, or to be used in large numbers, provide an additional rationale for their selection and their numbers. Explain why the research goals cannot be accomplished using an alternative model.
3. Describe the procedures for ensuring the discomfort, distress, pain, and injury will be limited to that which is unavoidable in the conduct of scientifically sound research. Describe the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices where appropriate to minimize discomfort, distress, pain, and injury.
4. Indicate whether vertebrate animals are euthanized and if the method is consistent with the recommendations of the Panel on Euthanasia of the American Veterinary Medical Association. If not, present a justification for not following the recommendations.

NOTE: DRC uses the “Just-In-Time” method for required approvals. Therefore, before funding can be distributed, appropriate Animal Care approval signature must be provided to the DRC on the application cover page.

Although no specific page limitation applies to this section of the application, be succinct.

H. Consultants/Collaborators. Attach an appropriate letter from each individual confirming his or her role in the project. Include an NIH style biographical sketch for each.

I. Literature Cited. Cite references with the style used by *Diabetes* (see <http://diabetes.diabetesjournals.org>). Briefly, cite references sequentially by numbers (in parentheses) in the body of the application and list the citations in numerical order in the Literature Cited section. Include all authors and full titles. Be selective, citing only those references that you consider directly relevant to your proposal. **Do not exceed two pages.**

NOTE: Do not attach appendices, reprints, or preprints to the application. These will be discarded and not reviewed.

--- APPENDIX A ---

OMB No. 0925-0001 and 0925-0002 (Rev. 09/17 Approved Through 03/31/2020)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. DO NOT EXCEED FIVE PAGES.

NAME:

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

POSITION TITLE:

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

INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	Completion Date MM/YYYY	FIELD OF STUDY

A. Personal Statement

Briefly describe why you are well-suited for your role(s) in the project described in this application. The relevant factors may include aspects of your training; your previous experimental work on this specific topic or related topics; your technical expertise; your collaborators or scientific environment; and your past performance in this or related fields (you may mention specific contributions to science that are not included in Section C). Also, you may identify up to four peer reviewed publications that specifically highlight your experience and qualifications for this project. If you wish to explain impediments to your past productivity, you may include a description of factors such as family care responsibilities, illness, disability, and active duty military service.

B. Positions and Honors

List in chronological order previous positions, concluding with the present position. List any honors. Include present membership on any Federal Government public advisory committee.

C. Contribution to Science

Briefly describe up to five of your most significant contributions to science. For each contribution, indicate the historical background that frames the scientific problem; the central finding(s); the influence of the finding(s) on the progress of science or the application of those finding(s) to health or technology; and your specific role in the described work. For each of these contributions, reference up to four peer-reviewed publications or other non-publication research products (can include audio or video products; patents; data and research materials; databases; educational aids or curricula; instruments or equipment; models; protocols; and software or netware) that are relevant to the

described contribution. The description of each contribution should be no longer than one half page including figures and citations.

Also provide a URL to a full list of your published work as found in a publicly available digital database such as SciENcv or My Bibliography, which are maintained by the US National Library of Medicine.

D. Research Support

List both selected ongoing and completed research projects for the past three years (Federal or non-Federally-supported). *Begin with the projects that are most relevant to the research proposed in the application.* Briefly indicate the overall goals of the projects and responsibilities of the key person identified on the Biographical Sketch. Do not include number of person months or direct costs.

BIOGRAPHICAL SKETCH - EXAMPLE

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: Hunt, Morgan Casey

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

POSITION TITLE: Associate Professor of Psychology

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

INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	Completion Date MM/YYYY	FIELD OF STUDY
University of California, Berkeley	B.S	05/1990	Psychology
University of Vermont	Ph.D.	05/1996	Experimental Psychology
University of California, Berkeley	Postdoctoral	08/1998	Public Health and Epidemiology

A. Personal Statement

I have the expertise, leadership, training, expertise and motivation necessary to successfully carry out the proposed research project. I have a broad background in psychology, with specific training and expertise in ethnographic and survey research and secondary data analysis on psychological aspects of drug addiction. My research includes neuropsychological changes associated with addiction. As PI or co-Investigator on several university- and NIH-funded grants, I laid the groundwork for the proposed research by developing effective measures of disability, depression, and other psychosocial factors relevant to the aging substance abuser, and by establishing strong ties with community providers that will make it possible to recruit and track participants over time as documented in the following publications. In addition, I successfully administered the projects (e.g. staffing, research protections, budget), collaborated with other researchers, and produced several peer-reviewed publications from each project. As a result of these previous experiences, I am aware of the importance of frequent communication among project members and of constructing a realistic research plan, timeline, and budget. The current application builds logically on my prior work. During 2005-2006 my career was disrupted due to family obligations. However, upon returning to the field I immediately resumed my research projects and collaborations and successfully competed for NIH support.

- Merryle, R.J. & Hunt, M.C. (2004). Independent living, physical disability and substance abuse among the elderly. *Psychology and Aging*, 23(4), 10-22.
- Hunt, M.C., Jensen, J.L. & Crenshaw, W. (2007). Substance abuse and mental health among community-dwelling elderly. *International Journal of Geriatric Psychiatry*, 24(9), 1124-1135.
- Hunt, M.C., Wiechelt, S.A. & Merryle, R. (2008). Predicting the substance-abuse treatment needs of an aging population. *American Journal of Public Health*, 45(2), 236-245. PMID: PMC9162292
- Hunt, M.C., Newlin, D.B. & Fishbein, D. (2009). Brain imaging in methamphetamine abusers across the life-span. *Gerontology*, 46(3), 122-145.

B. Positions and Honors

Positions and Employment

1998-2000 Bethesda, MD	Fellow, Division of Intramural Research, National Institute of Drug Abuse,
2000-2002	Lecturer, Department of Psychology, Middlebury College, Middlebury, VT
2001-	Consultant, Coastal Psychological Services, San Francisco, CA
2002-2005 Louis, MO	Assistant Professor, Department of Psychology, Washington University, St. Louis, MO
2007- Louis, MO	Associate Professor, Department of Psychology, Washington University, St. Louis, MO

Other Experience and Professional Memberships

1995-	Member, American Psychological Association
1998-	Member, Gerontological Society of America
1998-	Member, American Geriatrics Society
2000-	Associate Editor, Psychology and Aging
2003-	Board of Advisors, Senior Services of Eastern Missouri
2003-05	NIH Peer Review Committee: Psychobiology of Aging, ad hoc reviewer
2007-11	NIH Risk, Adult Addictions Study Section, members

Honors

2003	Outstanding Young Faculty Award, Washington University, St. Louis, MO
2004	Excellence in Teaching, Washington University, St. Louis, MO
2009 Society	Award for Best in Interdisciplinary Ethnography, International Ethnographic Society

C. Contribution to Science

1. My early publications directly addressed the fact that substance abuse is often overlooked in older adults. However, because many older adults were raised during an era of increased drug and alcohol use, there are reasons to believe that this will become an increasing issue as the population ages. These publications found that older adults appear in a variety of primary care settings or seek mental health providers to deal with emerging addiction problems. These publications document this emerging problem but guide primary care providers and geriatric mental health providers to recognize symptoms, assess the nature of the problem and apply the necessary interventions. By providing evidence and simple clinical approaches, this body of work has changed the standards of care for addicted older adults and will continue to provide assistance in relevant medical settings well into the future. I served as the primary investigator or co-investigator in all of these studies.
 - a. Gryczynski, J., Shaft, B.M., Merrylye, R., & Hunt, M.C. (2002). Community based participatory research with late-life addicts. *American Journal of Alcohol and Drug Abuse*, 15(3), 222-238.
 - b. Shaft, B.M., Hunt, M.C., Merrylye, R., & Venturi, R. (2003). Policy implications of genetic transmission of alcohol and drug abuse in female nonusers. *International Journal of Drug Policy*, 30(5), 46-58.
 - c. Hunt, M.C., Marks, A.E., Shaft, B.M., Merrylye, R., & Jensen, J.L. (2004). Early-life family and community characteristics and late-life substance abuse. *Journal of Applied Gerontology*, 28(2),26-37.

Physical disability, depression and substance abuse in the elderly

The goal of this study is to identify disability and depression trajectories and demographic factors associated with substance abuse in an independently-living elderly population.

Role: Co-Investigator

Faculty Resources Grant, Washington University

08/15/09-08/14/15

Opiate Addiction Database

The goal of this project is to create an integrated database of demographic, social and biomedical information for homeless opiate abusers in two urban Missouri locations, using a number of state and local data sources.

Role: PI

Completed Research Support

R21 AA998075

Hunt (PI)

01/01/11-12/31/13

Community-based intervention for alcohol abuse

The goal of this project was to assess a community-based strategy for reducing alcohol abuse among older individuals.

Role: PI

--- APPENDIX B ---

OTHER SUPPORT

Other Support includes all financial resources, whether Federal, non-Federal, commercial or institutional, available in direct support of an individual's research endeavors, including but not limited to research grants, cooperative agreements, contracts, and/or institutional awards. Prizes or gifts do not need to be included.

Format

NAME OF INDIVIDUAL

ACTIVE/PENDING

Project Number (Principal Investigator) Source Title of Project (or Subproject)	Dates of Approved/Proposed Project Annual Direct Costs	Person Months (Cal/Academic/ Summer)
The major goals of this project are...		

OVERLAP (summarized for each individual)

Samples

ANDERSON, R.R.

ACTIVE

2 R01 HL 00000-13 (Anderson) NIH/NHLBI Chloride and Sodium Transport in Airway Epithelial Cells	3/1/2012 – 2/28/2017 \$186,529	3.60 calendar
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The major goals of this project are to define the biochemistry of chloride and sodium transport in airway epithelial cells and clone the gene(s) involved in transport.

5 R01 HL 00000-07 (Baker) NIH/NHLBI Ion Transport in Lungs	4/1/2001 – 3/31/2012 \$122,717	1.20 calendar
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The major goal of this project is to study chloride and sodium transport in normal and diseased lungs.

R000 (Anderson) Cystic Fibrosis Foundation Gene Transfer of CFTR to the Airway Epithelium	9/1/2014 – 8/31/2017 \$43,123	1.20 calendar
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The major goals of this project are to identify and isolate airway epithelium progenitor cells and express human CFTR in airway epithelial cells.

PENDING

DCB 950000 (Anderson) National Science Foundation Liposome Membrane Composition and Function	12/1/2014 – 11/30/2016 \$82,163	2.40 calendar
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The major goals of this project are to define biochemical properties of liposome membrane components and maximize liposome uptake into cells.

OVERLAP

There is scientific overlap between aim 2 of NSF DCB 950000 and aim 4 of the application under consideration. If both are funded, the budgets will be adjusted appropriately in conjunction with agency staff.

RICHARDS, L.

NONE

HERNANDEZ, M.

ACTIVE

5 R01 CA 00000-07 (Hernandez) NIH/NCI Gene Therapy for Small Cell Lung Carcinoma	4/1/2010 – 3/31/2017 \$110,532	3.60 academic
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The major goals of this project are to use viral strategies to express the normal p53 gene in human SCLC cell lines and to study the effect on growth and invasiveness of the lines.

5 P01 CA 00000-03 (Chen) NIH/NCI Mutations in p53 in Progression of Small Cell Lung Carcinoma	7/1/2014 – 6/30/2016 \$104,428 (sub only)	1.80 academic 3.00 summer
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The major goals of this subproject are to define the p53 mutations in SCLC and their contribution to tumor progression and metastasis.

BE 00000 (Hernandez) American Cancer Society p53 Mutations in Breast Cancer	9/1/2014 – 8/31/2017 \$86,732	1.80 academic
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The major goals of this project are to define the spectrum of p53 mutations in human breast cancer samples and correlate the results with clinical outcome.

OVERLAP

Potential commitment overlap for Dr. Hernandez between 5 R01 CA 00000-07 and the application under consideration. If the application under consideration is funded with Dr. Hernandez committed at 3.60 person months, Dr. Hernandez will request approval to reduce her months on the NCI grant.

BENNETT, P.

ACTIVE

Investigator Award (Bennett) Howard Hughes Medical Institute Gene Cloning and Targeting for Neurological Disease Genes	9/1/2015 – 8/31/2017 \$581,317	9.00 calendar
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This award supports the PI's program to map and clone the gene(s) implicated in the development of Alzheimer's disease and to target expression of the cloned gene(s) to relevant cells.

OVERLAP: None