

Formatting Requirements:

- At least ½ inch margins
- Size 11 font (smallest you can use)
- Arial, Helvetica, Palatino Linotype or Georgia fonts

Attachments (Attachment 1 for specifics on each section):

- 1) Intro to Application (only for resubmissions)
- 2) Specific Aims (1 page limit)
- 2a) Research Plan (do not repeat Specific Aims, 24 page limit)
- 3) Progress Report (only for renewals)
- 4) Human Subjects (if applicable, no limit)
- 5) Vertebrate Animals (if applicable, no limit)
- 6) Multiple PD/PI Leadership Plan (typically not needed)
- 7) Consortium/Contractual Agreements (typically not needed)
- 8) Director's Letter (I will obtain this for you)
- 8a) R&D Committee Letter (typically not needed)
- 9) Checklist (I will obtain this for you)
- 10) Abbreviations (all abbreviations used in the research plan)
- 11) Financial Disclosure (statement of financial conflict of interest with any PI for proposed research)
- 12) Any other appendices you may want to attach (questionnaires, publications)
 - Up to 3 of the following types of publications:
 1. Manuscripts and/or abstracts accepted for publication but not yet published
 2. Manuscripts and/or abstracts published, but a free, online, publicly available journal link is not available
 3. Patents directly relevant to the project

1) Project Summary/Abstract (40 line limit)

The Project Summary/Abstract is meant to serve as a succinct and accurate description of the proposed work when separated from the application. Describe concisely the research design and methods for achieving the stated goals. This section should be informative to other persons working in the same or related fields and insofar as possible understandable to a scientifically or technically literate reader. Avoid describing past accomplishments and the use of the first person.

Do not begin the Project Summary with the extra words that state: "Project Summary" or "Abstract" – this is not needed as the file is bookmarked internally by eRA.

2) Project Narrative (10 line limit)

This must describe the relevance of the proposed research to Veterans' health and/or healthcare issues. It does not refer to the Research Plan. A maximum of 10 lines of text may be used.

Do not begin the Project Narrative with the extra words that state: "Project Narrative" – this is not needed as the file is bookmarked internally by eRA.

3) Bibliography & References Cited (4 page limit)

4) Facilities and Other Resources (what is currently available for the proposal, no limit)

5) Equipment (that is currently available to you, no limit)

6) Biosketches on all key personnel (**Attachment 2**)

7) Other support pages on all key personnel (**Attachment 3**)

8) Budget Justification (**Attachment 4**)

Attachment and Required File Name	Instructions
<p>1. Introduction to Application (for Resubmission only)</p> <p>01_VA_Intro.pdf</p>	<p>Use only if you are submitting a Resubmission application (Cover Component Item 8) for a previously reviewed application that was submitted through Grants.gov. The Introduction may not exceed three pages for resubmission applications.</p>
<p>2. Specific Aims</p> <p>02_VA_Specific_Aims.pdf</p>	<p>Concisely state the goals of the proposed research and summarize the expected outcome(s), including the impact that the results of the proposed research will exert on the research field(s) involved.</p> <p>Succinctly list the specific objectives of the research proposed, e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop new technology.</p> <p>This attachment is limited to 1 page.</p>
<p>2a. Research Plan</p> <p>02a_VA_Research_Plan.pdf</p>	<p>The Research Plan should include sufficient information needed for evaluation of the project, independent of any other document (e.g., previous application). Be specific and informative, and avoid redundancies.</p> <p>In general, the Research Plan will contain a description of the Background and Significance, Preliminary Studies and Current Status of the Field, and Research Design and Methods.</p> <p>Do not repeat the Specific Aims in the research plan.</p> <p>A Progress Report must be included for renewal applications. Provide the beginning and ending dates for the period covered since the project was last reviewed competitively. Summarize the previous application's specific aims and the importance of the findings. Provide a succinct account of published and unpublished results, indicating progress toward their achievement.</p> <p>Additional and/or alternate sections/headings may be required for certain Funding Announcements. Each R&D Service will provide specific instructions about the required headings and content for the Research Plan in their posted Funding Announcements (RFAs).</p> <p>The Research Plan is limited to 24 pages for all R&D Services.</p>
<p>3. Progress Report Publication List</p> <p>03_Prog_Report_Pubs.pdf</p>	<p>For all renewal applications, provide a list of titles and complete citations for all publications, manuscripts accepted for publication, patents, and other printed materials that have resulted from the project since it was last reviewed competitively. Some Service-specific RFAs may indicate that this attachment is not required.</p> <p>For publicly available citations, URLs or PMC submission identification numbers may accompany the full reference. Note: copies of these publications are no longer accepted as appendix material.</p> <p>Do not include unpublished theses or abstracts/manuscripts submitted, but not accepted for publication.</p>
<p>4. Human Subjects</p> <p>04_Human_Subjects.pdf</p>	<p>This attachment is required if you checked the box marked "Yes" for Question 1 (Are Human Subjects Involved?) on the Other Project Information Component. This section covers the information regarding the Protection of Human Subjects. In this attachment, the following headings should be used and fully described. Refer to SF 424 Part II for additional information on Human Subjects Research Requirements.</p> <p>Do not include Informed Consent forms, even if already approved by the IRB. These documents will be requested as part of the JIT process.</p> <p>Fully describe:</p>

Attachment and Required File Name	Instructions
	<ol style="list-style-type: none"> 1. Risk to Subjects. <ul style="list-style-type: none"> • <i>Human Subjects Involvement and Characteristics.</i> Describe the anticipated number, age range, and health status of the subject population. Identify the criteria for inclusion or exclusion of any subpopulation. Explain the rationale for the involvement of special classes of subjects or others who may be considered vulnerable populations. Indicate whether all subjects recruited for the study will be Veterans or whether non-Veterans will also be included. Justification must be provided for use of non-Veteran subjects in VA-ORD funded research projects. • <i>Sources of Materials.</i> Identify the sources of research material and indicate whether the material or data will be obtained specifically for research purposes or if existing specimens, records, or data will be used. • <i>Potential Risks.</i> Describe the potential risks to subjects (physical, psychological, social, legal, or other) and assess their likelihood and seriousness to the subjects. Differentiate therapeutic risk from research risk. 2. Adequacy of Protection from Risk <ul style="list-style-type: none"> • <i>Recruitment and Informed Consent.</i> Describe plans for the recruitment of subjects and the process for obtaining informed consent. NOTE: The informed consent document may not be submitted at this time. • <i>Protection Against Risk.</i> Describe the planned procedures for preventing or minimizing potential risks (including risks to confidentiality and data security). Specify methods for collecting data on complications of treatment, adverse and severe adverse events for safety monitoring.
4. Human Subjects (cont)	<ol style="list-style-type: none"> 3. Potential benefits of research to subjects and others. Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and others. 4. Importance of knowledge to be gained. Data and Safety Monitoring Plan. Describe the plans for monitoring the safety of participants and the accuracy and integrity of the data. Describe steps to ensure adequate subject recruitment and enrollment, including if necessary, replacement of study sites. <p>In addition, the inclusion of women, minorities and/or children must be addressed; children cannot be included in VA-approved research conducted by VA investigators while on duty, or conducted at VA facilities or approved off-site locations, unless a waiver has been granted by the Chief Research and Development Officer.</p>
5. Vertebrate Animals 05_VA_Animals.pdf	<p>An attachment addressing the following five key points is required if you checked the box marked “Yes” for Question 2 (Are Vertebrate Animals Used?) on the Other Project Information Component.</p> <p>When research involving vertebrate animals will take place at other performance site(s), provide this information before discussing the five points. Although there is no specific page limitation, be succinct.</p> <ol style="list-style-type: none"> 1. Provide a detailed description of the proposed use of the animals. Identify the species, strains, ages, sex, and numbers of animals to be used in the proposed work. 2. Justify the use of animals, the choice of species, and the numbers to be used. If animals are in short supply, costly, or to be used in large numbers, provide an additional rationale for their selection and numbers. 3. Provide information on the veterinary care of the animals involved. 4. Describe the procedures for ensuring that discomfort, distress, pain, and injury will be limited to that which is unavoidable in the conduct of

Attachment and Required File Name	Instructions
	<p>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.</p> <p>5. Describe any method of euthanasia to be used and the reasons for its selection. State whether this 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.</p> <p>Save this information in a single file. See instructions for attaching PDF documents in Item 12 above.</p>
<p>6. Multiple PD/PI Leadership Plan</p> <p>06_VA_Multiple_PI.pdf</p>	<p>A leadership plan is required if more than one individual is assigned the role of PD/PI in Section A of the Budget Component.</p> <p>Non-VA investigators may not be assigned the PD/PI role.</p> <p>A rationale for choosing a multiple PD/PI approach should be described. The governance and organizational structure should be described, including communication plans and procedures for resolving conflicts. The shared administrative, technical, and scientific responsibilities for the project or program should be delineated for the PIs. The use of multiple PD/PI's must not be used to avoid budget caps (restrictions) described in any VA-ORD Funding Announcement. Investigators should discuss the inclusion of multiple PD/PI's with appropriate R&D Service staff prior to submission of their application.</p> <p>Save this information in a single file.</p>
<p>7. Consortium/Contractual Agreements</p> <p>07_VA_Agreements.pdf</p>	<p>This attachment should only be used to describe existing consortium or contractual agreements that are relevant to the proposed research.</p> <p>It should not be used to describe or to justify the required sub-award budgets for multisite projects.</p> <p>Explain the programmatic, fiscal, and administrative arrangements that exist between the applicant VA medical center and any consortium or contractual organization(s).</p> <p>New consortium or contractual agreements will not be considered binding to VA contractually.</p>
<p>8. Director's Letter</p> <p>08_VA_Director_Letter.pdf</p> <p>The required file name for this attachment may generate a warning message from eRA Commons</p>	<p>A signed copy of the letter of support from the medical center Director must be submitted as a separate attachment and must include the following:</p> <ul style="list-style-type: none"> • A statement that the Director understands the impact of the proposed research on the facility's organization and that he/she endorses the project. • Where the research will be conducted, if any off-site waivers are included with the application, and that the VA space described in the application and necessary support of the VA facility will be available. <p>If a clinician PD/PI's appointment is to start at the time of funding, the VA medical center Director's memorandum must contain a statement indicating that the PD/PI will be given a VA-paid clinical appointment of at least 5/8ths time.</p> <p><u>Proposals submitted without this attachment will not be accepted for review. This is a checklist item.</u></p>
<p>8a. Letters of Support</p> <p>08a_VA_Letters.pdf</p> <p>The required file name may generate a warning message from eRA Commons concerning the attachment</p>	<p>Attach appropriate letters here from all individuals confirming their roles in the project and rate/charge for consulting services. Also, include copies of all approved off-site waivers (if applicable). This is a checklist item.</p> <p>Note: Biosketches should be included in Senior/Key Person Section, not in Letters of Support.</p>

Attachment and Required File Name	Instructions
<p>name</p> <p>9. Checklist 09_VA_Checklist.pdf The required file name for this attachment may generate a warning message from eRA Commons concerning the attachment name</p>	<p>Attach a completed copy of the Electronic Merit Review Submission Checklist. Check only the applicable boxes. Use the checklist to verify that all content and formatting requirements have been met and that the final application is complete.</p> <p>Do not check a box until you are sure that the item has been carefully examined and is correct. Proposals with incorrectly checked boxes may not be accepted for review</p> <p>Proposals submitted without this attachment will not be accepted for review.</p>
<p>10,11... Appendices 10_VA_Appendix_1.pdf 11_VA_Appendix_2.pdf 12_VA_Appendix_3.pdf (additional attachments as needed: same file name format)</p>	<p>Only one copy of an appendix is necessary. A summary sheet listing all of the items included in the appendix may be included in the first appendix attachment; this is encouraged, but not required.</p> <p>Do not include Informed Consent forms as an appendix, even if already approved by the IRB.</p> <p>New, resubmission, and renewal applications may include the following materials in the Appendices.</p> <ul style="list-style-type: none"> • Up to 3 of the following types of publications: <ul style="list-style-type: none"> ○ Manuscripts and/or abstracts accepted for publication but <u>not yet published</u>. ○ Manuscripts and/or abstracts published, but a free, online, <u>publicly available journal link is not available</u>. ○ Patents <u>directly relevant to the project</u>. • Surveys, questionnaires, data collection instruments, clinical protocols, and informed consent documents may be submitted as PDF attachments. • Photographs or color images of gels, micrographs, etc., are no longer accepted as Appendix material. These images must be included in the Research Plan and will count toward the 24-page limit. Images embedded in publications are still allowed. <p>Similar appendix material should be combined within an attachment. For example, please place all accepted, but not yet published, manuscripts in one attachment.</p>
<p>10,11... Appendices (cont) For Appendix names only: If descriptive text is included in an attachment name before the ".PDF" (i.e., "_Surveys.PDF"), you will receive a warning message from eRA concerning the attachment name. This warning can be safely ignored.</p>	<p>Do not include unpublished theses or abstracts/manuscripts that have been submitted but not yet accepted for publication.)</p> <p>Published manuscripts and/or abstracts that have a free, publicly available online journal link should no longer be included in the appendix material. The URL or PMC submission identification numbers should be included along with the full reference in the Bibliography and References cited section, the Progress Report Publication List section, and/or the Biographical Sketch section.</p> <p>For materials that cannot be submitted electronically or materials that cannot be converted to PDF format (e.g., medical devices, prototypes, DVDs, CDs), applicants should contact the SRO for instructions following notification of assignment of the application to an SRG. Applicants are encouraged to be as concise as possible and submit only information essential for the review of the application.</p> <p>Do not use Appendices to circumvent the page limitations of the Research Plan. An application that does not observe the stated page limitations will be administratively withdrawn from review.</p>

BIOGRAPHICAL SKETCH

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

NAME Hunt, Virginia Lively	POSITION TITLE Associate Professor of Psychology		
eRA COMMONS USER NAME (credential, e.g., agency login) huntvl			
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	MM/YY	FIELD OF STUDY
University of California, Berkeley	B.S.	05/90	Psychology
University of Vermont	Ph.D.	05/96	Experimental Psychology
University of California, Berkeley	Postdoctoral	08/98	Public Health and Epidemiology

A. Personal Statement

The goal of the proposed research is to investigate the interaction between drug abuse and normal aging processes. Specifically, we plan to measure changes in cognitive ability and mental and physical health across a five-year period in a group of older drug users and matched controls. I have the expertise, leadership and motivation necessary to successfully carry out the proposed work. I have a broad background in psychology, with specific training and expertise in key research areas for this application. As a postdoctoral fellow at Berkeley, I carried out ethnographic and survey research and secondary data analysis on psychological aspects of drug addiction. At the Division of Intramural Research at the National Institute on Drug Abuse (NIDA), I expanded my research to include neuropsychological changes associated with addiction. As PI or co-Investigator on several previous 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. 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, and I have chosen co-investigators (Drs. Gryczynski and Newlin) who provide additional expertise in cognition, gerontology and geriatrics. In summary, I have a demonstrated record of successful and productive research projects in an area of high relevance for our aging population, and my expertise and experience have prepared me to lead the proposed project.

Time and Effort Statement (for PI only): ___% on Research, ___% on Clinical, ___% on Teaching/Mentoring, ___% on Administration.

B. Positions and Honors

Positions and Employment

1998-2000	Fellow, Division of Intramural Research, National Institute of Drug Abuse, Bethesda, MD
2000-2002	Lecturer, Department of Psychology, Middlebury College, Middlebury, VT
2001-	Consultant, Coastal Psychological Services, San Francisco, CA

2002-2005 Assistant Professor, Department of Psychology, Washington University, St. Louis, MO
2005- 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
2003-04 NIH Peer Review Committee: Psychobiology of Aging, ad hoc reviewer
2005-09 NIH Risk, Adult Addictions Study Section, member

Honors

2003 Outstanding Young Faculty Award, Washington University, St. Louis, MO
2005 Excellence in Teaching, Washington University, St. Louis, MO
2008 Award for Best in Interdisciplinary Ethnography, International Ethnographic Society

C. Selected Peer-reviewed Publications (Selected from 42 peer-reviewed publications)

Most relevant to the current application

1. Merrylye, R.J. & Hunt, V.L. (2004). Independent living, physical disability and substance abuse among the elderly. *Psychology and Aging*, 23(4), 10-22.
2. Hunt, V.L., Jensen, J.L. & Crenshaw, W. (2007). Substance abuse and mental health among community-dwelling elderly. *International Journal of Geriatric Psychiatry*, 24(9), 1124-1135.
3. Hunt, V.L., Wiechelt, S.A. & Merrylye, R. (2008). Predicting the substance-abuse treatment needs of an aging population. *American Journal of Public Health*, 45(2), 236-245. PMID: PMC9162292
4. Hunt, V.L., Newlin, D.B. & Fishbein, D. (2009). Brain imaging in methamphetamine abusers across the life-span. *Gerontology*, 46(3), 122-145.
5. Hunt, V.L. & Sher, K.A. (2009). Successful intervention models for older drug-abusers: Research across the life-span. *American Psychologist*, in press. NIHMSID: NIHMS99135

Additional recent publications (in chronological order)

1. Gryczynski, J., Shaft, B.M., Merrylye, R., & Hunt, V.L. (2002). Community based participatory research with late-life addicts. *American Journal of Alcohol and Drug Abuse*, 15(3), 222-238.
2. Shaft, B.M., Hunt, V.L., 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.
3. Hunt, V. L., 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.
4. Hunt, V.L., Merrylye, R. & Jensen, J.L. (2005). The effect of social support networks on morbidity among elderly substance abusers. *Journal of the American Geriatrics Society*, 57(4), 15-23.
5. Hunt, V.L., Pour, B., Marks, A.E., Merrylye, R. & Jensen, J.L. (2005). Aging out of methadone treatment. *American Journal of Alcohol and Drug Abuse*, 15(6), 134-149.
6. Hunt, V.L, Marks, A.E., Venturi, R., Crenshaw, W. & Ratonian, A. (2006). Community-based intervention strategies for reducing alcohol and drug abuse in the elderly. *Addiction*, 104(9), 1436-1606. PMID: PMC9000292
7. Merrylye, R. & Hunt, V.L. (2006). Randomized clinical trial of cotinine in older nicotine addicts. *Age and Ageing*, 38(2), 9-23. PMID: PMC9002364
8. Hunt, V.L., Jensen, J.L. & Merrylye, R. (2008). *The aging addict: ethnographic profiles of the elderly drug user*. NY, NY: W. W. Norton & Company.
9. Hunt, V.L. (2009). Contrasting ethnicity with race in the older alcoholic. *The Journals of Gerontology Series B: Psychological Sciences and Social Sciences*, in press. PMID: PMC Journal – In Process.
10. Hunt, V.L. (2009). Intervening successfully with the older methadone patient. *Journal of Applied Gerontology*, 13(4), 67-79.

OTHER SUPPORT

Last Name, First Name

Active

R01 HL 058812-14 (Last Name) 04/01/07 – 03/31/13 3.6 calendar
NIH/NHLBI \$0

The major goal of this grant is to identify mechanisms that regulate ENaC trafficking to and from the cell surface.

R01 HL72256-08 (Last Name) 03/01/09 - 02/28/14 4.2 calendar
NIH/NHLBI \$222,750

The goal of this proposal is to investigate mechanisms that regulate gating of the epithelial sodium channel.

Pending

Merit Review (Last Name) 10/01/12 - 09/30/16 2.4 calendar
VA \$200,000

Epithelial Sodium Channel Trafficking

The goal of this grant is understand mechanisms that regulate ENaC trafficking in the endocytic and biosynthetic pathways.

Overlap

There is no scientific, budgetary or commitment overlap with this application.

BUDGET JUSTIFICATION

Personnel:

Investigator name, M.D., Principal Investigator (__ calendar months), will be responsible for implementation of the proposed studies, supervision of personnel, writing of manuscript and publication of the findings. They will devote 7.5 calendar months effort to this project consistent with their __/8ths VA appointment. Commensurate salary support and fringe benefits are requested.

Technician Name, Staff scientist (12 calendar months). (Name) is an accomplished microbiologist. They will be responsible for studies in Aims 1 and 3 of this proposal and will devote all of their time and effort to this project. Commensurate salary support and fringe benefits are requested (\$__,__).

Technician Name, B.S., Research lab technician (__ calendar months). They are a molecular biologist. They will perform studies in Aim 2 and will devote __% effort to this project. Commensurate salary and fringe benefits are requested (\$__,__).

Supplies:

Tissue culture supplies and other disposable plastic labware:	\$ 9,000
Antibodies for microscopy, flow cytometry and immunoblotting:	\$10,000
Reagents for RNA extraction and qPCR:	\$ 7,000
Signaling inhibitors, buffers and other reagents	\$ 9,000

Publication charges:

Funds are requested to cover the cost of publishing our findings:	\$ 2,828
---	----------

Other expenses:

Ui Microcopy fees:

We request funds to cover use of light and electron microscopes at \$50/hr x 100 hr: \$5,000	\$ 5,000
--	----------

Blood donor fees:

Peripheral blood leukocytes obtained from normal donors are essential for our studies. We request funds to cover the cost of two donors per week (\$20 x 100 = \$2,000)	\$ 2,000
---	----------