## NIH Funding Opportunity No. PAR-09-220

SBIR/STTR Phase I

http://www.grants.nih.gov/grants/guide/pa-files/PAR-09-220.html

Application Due Date: 5:00 p.m. Mountain Time on December 5, 2010 (really the 6<sup>th</sup>).

Applications MUST be submitted via Grants.gov (Leslie will complete) and will require the following:

Registration of PI on eRA Commons is mandatory and will be completed by Larry or Leslie Budget not to exceed \$150,000 per year for a two year project period. Multiple PIs are allowed and each person MUST be registered on eRA Commons.

- Title and short name (or Leslie will create one)
- Font size no smaller than 11pt using Arial, Helvetica, Palatino, Linotype or Georgia on 8½ x 11 pages. All text must be in Black, figures may have color. NO INFORMATION MAY APPEAR IN THE HEADER OR FOOTER. A header will be system generated with PI name; the footer will be system generated with sequential page numbers.
- SF424 (basic application information) (WILL BE COMPLETED BY LESLIE)

Info required from the PI to assist Leslie in completing the SF424:

- 1. Descriptive title of applicant's project.
- 2. Are Human Subjects involved?
- 3. Does the project have an effect or potential impact on the environment?
- 4. Are there any international collaborators?
- 5. Does this application include subcontracts with Federal Laboratories or other Federal Agencies?
- 6. Has the PI submitted proposals for essentially equivalent work under Federal program solicitations or received Federal awards for essentially equivalent work?
- 7. If you have a subcontract, I will need the address where the work will be completed.
- 8. Will this project have any income from outside sources during the project period? If yes, explain source and anticipated amount.
- **Project Summary (abstract) no longer than 30 lines of text** (this document must be a separate PDF file named "Short name\_Summary.pdf").

The Project Summary must contain a summary of the proposed activity suitable for dissemination to the public. It should be a self-contained description of the project and should contain a statement of objectives and methods to be employed. It should be informative to other persons working in the same or related fields and insofar as possible understandable to a scientifically or technically literate lay reader. It is meant to serve as a succinct and accurate description of the proposed work when separated from the application. State the application's broad, long-term objectives and specific aims, making reference to the health relatedness of the project (i.e., relevance to the **mission of the agency**). Describe concisely the research design and methods for achieving the stated goals. This Summary must not include any proprietary/confidential information.

### • Project Narrative

For NIH and other PHS agencies applications, this attachment will reflect the second component of the Project Summary. The second component of the Project Summary/Abstract (i.e., "Description") is Relevance. Using no more than two or three sentences, describe the relevance of this research to public health. In this section, be succinct and use plain language that can be understood by a general, lay audience

## • Bibliography & References Cited

Provide a bibliography of any references cited in the Project Narrative. This section is required for submissions to NIH and other PHS agencies.

### • Facilities & Other Resources

This information is used to assess the capability of the organizational resources available to perform the effort proposed. Identify the facilities to be used (Laboratory, Animal, Computer, Office, Clinical and Other). No special form is required but this section must be completed and attached as a pdf

#### • Equipment

List major items of equipment already available for this project and, if appropriate identify location and pertinent capabilities.

# • Biographical sketch of each senior/key person (separate pdf for each person)

**Senior/Key Personnel** is defined as all individuals who contribute in a substantive, meaningful way t50 the scientific development or execution of the project, whether or not salaries are requested. Post docs should be included if they meet the definition of key personnel.

#### No more than 4 pages per bio (using format included with this summary

**Current and Pending support** should be included (listing should include: Total award amount and number of person months per year to be devoted to the project).

(**Note to Leslie**: other than PI, key people to be listed in alpha order. Must enter Commons username in Credential field )

• **Budget** (WILL BE DONE BY LESLIE with PI input) maximums of \$750,000 total and \$375,000/first yr **Budget must be created in two – 1yr increments** 

Leslie will need to know the following to create the budget:

- 1. who will work on the project (approximate % of time)
- 2. travel, to where, for how long, and for how many people
- 3. subcontract amount if applicable
- 4. any other expenses (equipment or materials)

Please remember to give Leslie info for each year of the proposed budget

## **Budget justification:**

Use the budget justification to provide the additional information requested in each budget category (personnel, travel, etc) (travel must be related to the needs of the project and include purpose, destination, dates of travel and number of persons for each trip) and any other information you wish to submit to support your budget request. Use this section to also list the names, role (e.g., PostDoc or Graduate Student), associated months, salary and fringe benefits for all Postdoctoral Associates and Graduate Students included. Include a justification for any significant increases or decreases from the initial year budget. If the application includes a subaward/consortium budget, a separate budget justification is submitted for that budget. Explain the basis and the amount requested for the fee in the budget justification

• **Budgets for sub awardees** (including research institutions such as federal labs) contact Leslie for Adobe file that must be filled out by Subcontractor and returned to us for upload into application package. This package will contain their budget justification.

## • PHS398 forms

### **Optional Cover Letter**

Applicants are encouraged to include a cover letter with the application. The cover letter is only for internal agency use and will not be shared with peer reviewers. The letter should contain any of the following information that applies to the application:

- 1. Application title.
- 2. Funding Opportunity (PA or RFA) title of the NIH initiative.
- 3. Request of an assignment (referral) to a particular <u>awarding component(s)</u> or <u>Scientific Review</u> Group (SRG). The PHS makes the final determination.
- 4. List of people (e.g., competitors) who should not review your application and why.
- 5. Disciplines involved, if multidisciplinary.
- 6. For late proposals include specific info regarding the timing and reason for the delay.
- 7. When submitting a 'Changed/Corrected' application, explain the reason for the corrections and include the text from all previous cover letters.
- 8. Explanation of any sub award budgets that are not active for all periods of the proposed project.
- 9. Statement that you have attached any required agency approval documentation for the type of application submitted. (to attach approval docs-append those to your CoverLetterFile and upload as one attachment.

## **Cover Page Supplemental Component (to be completed by Leslie)**

## Research Plan Component \*\*\*GUTS OF YOUR PROPOSAL\*\*\*\*

PAGE LIMIT – sections 2-5 no more than 15 pages. (section 1 only for re-submissions) Applicants are encouraged to construct the Research Plan as a single document, separating sections into distinct PDF attachments just before uploading the files to better monitor formatting.

- 1. This section only used for re-submissions or revisions
- 2. **Specific Aims** objectives of effort, including technical questions you will try to answer to determine the feasibility of the proposed research-**1 page**
- 3. **Research Strategy**-address the following in order:
  - a. Significance
  - b. Innovation
  - c. Approach
- 4. Inclusion Enrollment Report applicable for Phase II only
- 5. Progress Report Publication List- Phase II only
- 6. Human Subject Sections 6-9
- 10 Vertebrate Animals -
- 11. Select Agent Research hazardous biological agents
- 12. Multiple PI Leadership Plan only if designating multiple PIs
- 13. Consortium/Contractual Arrangements a minimum of 2/3<sup>rd</sup> of the effort must be completed by Tech-X. Use this section to explain the programmatic, fiscal and administrative arrangements to be made between the applicant and any other organization.
- 14. Letters of Support letters from all individuals confirming their roles in the project. Consultants' letters should include their rate for consultant services.
- 15. Resource Sharing Plan –
- 16. Appendix-files may be attached such as Manuscripts or abstracts for publications not yet published, or published but a free on-line access is not available or patents directly relevant to the project, data collection instruments. For PhI applications: Do not include appendices unless specifically requested by NIH.

# **Checklist Component** (to be completed by Leslie)

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

If yes, then need amount and source. (see Instructions page I-128 for listing of income examples)

## LISTING OF SEPARATE PDFs REQUIRED BY PI FOR SUBMISSION

- 1. Abstract labeled 'ShortName Summary.pdf'
- 2. Narrative labeled 'ShortName\_Narrative.pdf'
- 3. Bibliography & References Cited labeled 'ShortName References.pdf
- 4. Facilities & Other Resources labeled 'ShortName\_Facilities.pdf'
- 5. Equipment labeled 'ShortName Equipment.pdf'
- 6. Bio sketches `for PI and each key person listed labeled 'name.pdf'
- 7. Budget justification labeled 'Tech-X BudgetJustification.pdf'
- 8. Optional Cover Letter labeled 'ShortName\_CoverLtr.pdf'
- 9. Specific Aims labeled 'Aims.pdf'
- 10. Background and Significance labeled 'Background.pdf'
- 11. Preliminary Studies if applicable labeled 'Studies.pdf'
- 12. Research Design labeled 'Research.pdf'
- 13. Contractual Arrangements if applicable labeled 'Sub.pdf'
- 14. Letters of Support labeled 'name.pdf'
- 15. Sharing Plan labeled 'Sharing.pdf'

## **Notice of Proprietary Information**

Applicants are discouraged from submitting information considered proprietary unless it is deemed essential for proper evaluation of the application. However, when the application contains such information, identify the pages in the application that contain this information by marking those paragraphs or lines with an asterisk (\*) in the left-hand margin. Include a legend at the beginning of the Research Plan, similar to "The following sections marked with an asterisk contain proprietary/privileged information that (name of Applicant) requests not be released to persons outside the Government, except for purposes of review and evaluation."

Once the proposal is accepted (errors corrected) and it has been assembled by eRA Commons, we have two weekdays to view the submission. If everything looks acceptable no action is required on our part. If something did not get assembled correctly, we have the option to 'reject' the proposal and re-submit a Changed/Corrected application.

### **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	7.00001410 1	10100001 011 0	yonology
EDUCATION/TRAINING (Begin with baccalaureate or other initial residency training if applicable.)	l professional education,	such as nursing, inc	clude postdoctoral training and
INSTITUTION AND LOCATION	DEGREE (if applicable)	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 peerreviewed 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 coinvestigators (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.

#### **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. Merryle, 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. & Merryle, R. (2008). Predicting the substance-abuse treatment needs of an aging population. American Journal of Public Health, 45(2), 236-245. PMCID: 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 of importance to the field (in chronological order)

- 1. Gryczynski, J., Shaft, B.M., Merryle, 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., Merryle, 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., Merryle, 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., Merryle, 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., Merryle, 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. PMCID: PMC9000292
- 7. Merryle, R. & Hunt, V.L. (2006). Randomized clinical trial of cotinine in older nicotine addicts. Age and Ageing, 38(2), 9-23. PMCID: PMC9002364
- 8. Hunt, V.L., Jensen, J.L. & Merryle, 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. PMCID: PMC Journal In Process.
- 10. Hunt, V.L. (2009). Intervening successfully with the older methadone patient. Journal of Applied Gerontology, 13(4), 67-79.

## D. Research Support

## **Ongoing Research Support**

R01 DA942367-03 Hunt (PI) 09/01/07-08/31/12

Health trajectories and behavioral interventions among older substance abusers

The goal of this study is to compare the effects of two substance abuse interventions on health outcomes in an urban population of older opiate addicts.

Role: PI

R01 MH922731-05 Merryle (PI) 07/15/05-06/30/10

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 08/15/09-08/14/11

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.

# **Completed Research Support**

K02 AG442898 Hunt (PI) 09/01/06-

08/31/09

Drug Abuse in the Elderly

Independent Scientist Award: to develop a drug addiction research program with a focus on substance abuse among the elderly.

Role: PI

R21 AA998075 Hunt (PI) 01/01/04-

12/31/06

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